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Prospective Evaluation of Mesopic Night Vision and Night Vision Goggle Visual Acuity After Photorefractive Keratectomy (PRK)

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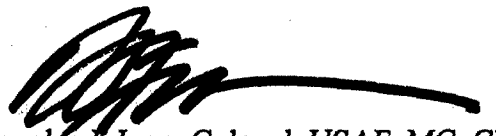

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14. ABSTRACT
The US Air Force PRK Study involved 98 non-flying, active duty volunteer personnel. All study subjects underwent a comprehensive array of vision tests. Baseline and post-operative data were collected at the Ophthalmology Branch of the Clinical Sciences Division of the USAF School of Aerospace Medicine, in partnership with the Air Force Research Laboratory and Wilford Hall Medical Center. This report covers results from pre- and post-operative night vision goggle (NVG) visual acuity testing. 65 treated subjects and 15 untreated controls completed all post-op visits through 12 months, and 52 treated subjects and 14 untreated controls through 24 months. NVG acuities were collected on a high contrast letter chart (Bailey-Lovie), and custom made grating charts. There was a statistically significant loss of letter acuity at the 4- and 6-month post-op visits for treated subjects but not controls. Acuity returned to baseline levels by 12 months. Mean loss of acuity for groups was typically only a few letters; however, treated subjects were more likely to lose than gain acuity beyond that predicted from repeatability studies with controls.

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INTRODUCTION

In a 31 Jul 1995 Memorandum entitled "Visual Enhancements for USAF Aviators," the Air Force Chief of Staff directed the Aerospace Ophthalmology Branch at the Armstrong Laboratory (now the USAF School of Aerospace Medicine), Brooks AFB TX, to begin to develop tests that can detect the complications of the then novel surgical procedure of PRK. The intent was to evaluate the potential safety and effectiveness of PRK surgery for USAF aviators and develop new aeromedical standards for Undergraduate Flying Training applicants. It should be stressed that aeromedical standards for operational flying are much different than standard clinical criteria in the civilian community. Problems that are termed minor or inconsequential by the civilian community may become potentially life threatening in military flight environments. USAF pilots and aviators are extremely valuable resources and their health and safety is vigilantly protected. The job of the Aerospace Ophthalmology Branch is to be a sentinel for aviators and ensure that nothing is done that might degrade vision or ultimately affect flying performance. Accordingly, a comprehensive scientific study was initiated to evaluate visual performance post-PRK with emphasis on detecting complications. This investigation of night mesopic and NVG visual performance was part of that comprehensive study; and, it was specifically designed to detect any negative effects from PRK that might potentially degrade night operational performance.

The USAF has an increasingly large proportion of its aviator population that require corrective lenses for flying duties, including currently almost 40% of pilots (1-3). This proportion is expected to increase in the future as a consequence of the more liberal refractive error entry criteria for flying over the last decade. Although eyeglasses have worked relatively well over the years (4), frames and spectacle lenses have inherent compatibility problems with basic life support equipment and other devices, e.g., flight helmets, oxygen masks, chemical/biological defense gear, NVGs, etc (5). Soft contact lenses, which were approved for Air Force aviators in the early 90's, provided an effective alternative to eyeglasses (6). However, in some instances corneal health was compromised and ametropic aircrew could not always achieve comfortable wear or good vision (7). Now refractive surgery, specifically photorefractive keratectomy (PRK), offers the USAF aviator a potentially viable alternative to reduce dependence on both spectacles and contact lenses (8).

Refractive surgery (RS) in general has attained a great deal of success in the civilian community; however, consistent reports about quality of vision (QoV) problems after the surgery have surfaced (9-16). This has driven a major paradigm shift in terms of defining success occupationally after refractive surgery (17-24). The USAF maintains great interest in these reports because any reduction in visual performance, no matter how subtle, may seriously impact mission safety and performance. Post-PRK QoV issues, especially problems that could degrade

vision at night (25-31), must be thoroughly evaluated in terms of potential mission impact. Critically important to night missions are any potential effects on mesopic low contrast visual acuity (VA), both with and without glare (32-35), and performance with night vision devices, especially Night Vision Goggles. Night Vision Goggle (NVG) visual acuity in aviators has been previously described and well documented (36-42), but little is known regarding NVG visual acuity performance after PRK. Early attempts to address this question were limited in both scope and duration (43, 44). The increase in military night operations and widespread use of night vision devices in essentially every night mission scenario, along with the ever-increasing numbers of flying personnel receiving PRK, mandates that NVG visual performance post-PRK be evaluated in terms of potential impact on flight safety and mission efficiency.

Mesopic low contrast night visual performance has particular relevance to military scientists for several reasons. First, many mission scenarios routinely involve dawn or dusk operations. Second, the nighttime battlefield is usually not dark enough for full scotopic conditions because there is considerable light from explosions, flares, muzzle flashes, afterburners, etc., and cultural lighting. Third, for most operational ambient light conditions, the output luminance from NVGs at the aviator's eyes is in the low photopic or mesopic range. Minimum operational standards for military NVG missions normally call for ambient light levels ranging from quarter moonlight to starlight only, although NVGs can provide significant function even below cloudy starlight (39, 42). The corresponding range of NVG output luminances is approximately 0.3 Foot-Lamberts (fL) under starlight conditions, and 1.2 fL) with quarter moon ambient lighting. This range encompasses visual function in the mesopic to low photopic region (45).

It is known that vision with NVGs is basically a mesopic contrast sensitivity function partially due to the inherent loss of resolution in the intensified image (46). The output of the NVG image intensifier P-43 phosphor, which is virtually monochromatic (Fig 1), ranges in brightness from low photopic to mesopic levels depending on the prevailing ambient illumination. Accordingly, resolution of objects with NVGs depends on detection of slight disparities in contrast within the low light and low contrast image generated on the phosphor screen. The low contrast effect can be easily demonstrated in the laboratory by viewing a very high contrast eyechart through NVGs at operationally equivalent light levels, i.e., quarter moon or starlight. The high contrast chart will appear to be a low contrast chart, and square wave gratings appear to be sine wave gratings, when viewed through NVGs. This can be easily verified using radiometric measurements similar to those reported in the methods section.

A concern is that many studies (10-13, 15, 19, 20, 25, and 32) have reported that night and/or mesopic low contrast VA was reduced after PRK. An early report from the UK (20) described a normal post-operative recovery sequence following PRK surgery to be poor vision for at least 1 week, watery vision for 1 month with significantly reduced contrast sensitivity, haze for one to three months although possibly more persistent, stabilization usually by 6 months but reduced contrast sensitivity for six to twelve months. A subsequent study (9), which employed smaller ablation zones, quantified the mean reduction in low contrast VA to be over 1-½ lines of letters at 1-year post-PRK. A more recent study (13) found that visual performance as tested with the Rabin Small Letter Low Contrast chart had not returned to pre-PRK normal in 81% of eyes at approximately one-year post-PRK. Another study (15) that used an intra-subject design reported that post-PRK corrected VA was reduced in the treated eye, as compared to the untreated fellow

eye, with the greatest difference found under night vision conditions, which were defined as low contrast and low illumination, i.e., mesopic levels.

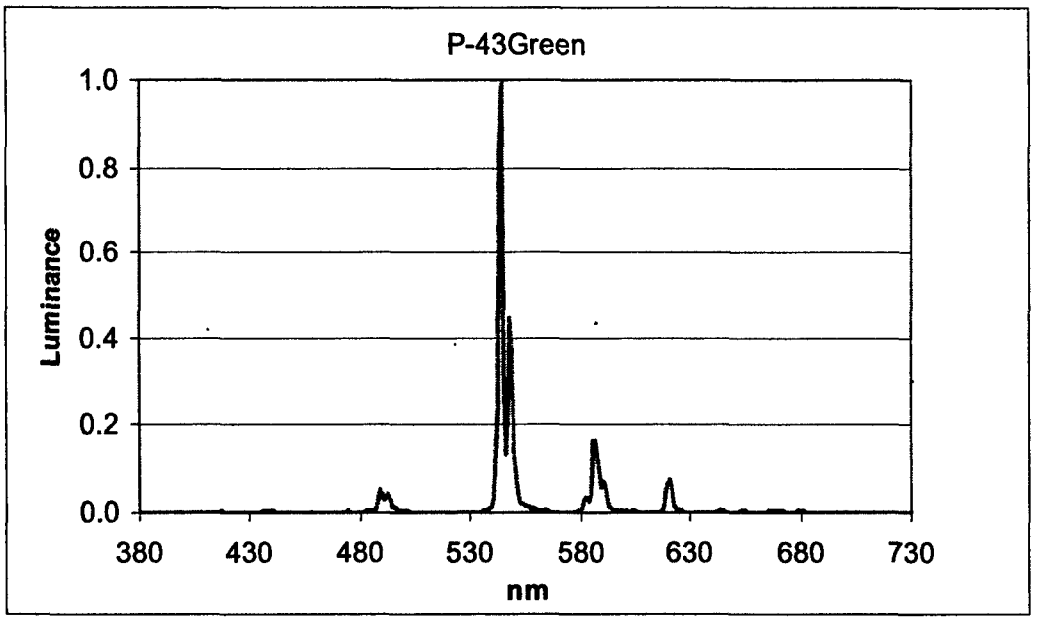


Figure 1. Output Emission of P-43 Phosphor in ANVIS-9 (F4949G) NVG.

Problems with night vision after PRK are exceedingly common. A survey (10) of 690 patients with bilateral PRK reported that over 31% of patients had a decrease in their night vision that many expressed as an increased difficulty driving at night especially with glare. A different report (20) found that at 12 months post-PRK, 5% of patients had what were described as significant problems with night vision, and over 38% had "minor" disturbances. Questions arise as to how significant these so-called minor disturbances might be in military operational night environments. An early study (11) of low to moderate myopes (USAF pilots fall in this refractive range) at 3 years post-PRK continued to report what was described as mildly decreased night vision, which was significant enough to cause asthenopia or eyestrain. Although some of these studies were conducted early on when smaller ablation zones were being used, one civilian author (12) stated in 2002 that with the increasing number of patients having RS, the increase in night vision problems, or reduced mesopic function, may become "a major public health issue".

It should also be pointed out that post-surgical testing in a typical civilian clinical setting often tends to grossly underestimate the existence of subtle QoV problems. This is because high contrast photopic VA is the generally accepted standard and it is often normal even when very significant reductions in night or mesopic vision, and contrast sensitivity, are present. Multiple studies (19, 47-51) reported that, even when subjects were given their best post-surgical optical correction, losses of low contrast VA were much greater than losses of standard high contrast VA. In addition, some people do not recognize potentially significant effects on visual performance in their daily lives (24). Even long-term impairment of low contrast vision, mesopic CS function, and/or glare disability may go undetected because the person may not drive much at night or work under the precise conditions that would make it recognizable (19).

What is unequivocal is that a certain percentage of patients after undergoing RS will have significant low contrast night and mesopic visual disturbances resulting from decreased CS, glare disability, and image degradation (12). Consequently, this has driven a major paradigm shift in the civilian sector that has sensitized these issues and their impact on QoV. This further translates into a potentially significant operational concern in those occupations that rely on optimal visual performance in impoverished visual conditions, such as military flight operations.

There are several possible causes of QoV problems post-PRK. A new test being evaluated to assess pilot's vision in the UK (25) found that night visual performance may be reduced in some subjects because of degraded retinal image quality from increased optical aberrations and scattered light. Degraded retinal image quality can also be caused by the presence of subepithelial corneal haze, which is more likely after PRK than other types of RS, corneal topographical irregularities such as irregular astigmatism, and higher order wavefront optical aberrations that are either unmasked or induced by the surgical procedure. In some cases, eliminating higher order optical aberrations may not be a good thing (52). Corneal irregular astigmatism and wavefront aberrations post-PRK have a very significant negative correlation with contrast sensitivity performance (15, 52). Custom corneal ablation for RS with wavefront-guided treatment is designed to correct some of the higher order optical aberrations (53), but currently it is not FDA approved for PRK. Early off-label use of custom wavefront-guided treatment has demonstrated potential for reducing some QoV problems; however, early custom-ablation LASIK studies do not identify a significant long-term benefit at this juncture. In the future, custom wavefront-guided surgery (18) may be routinely used to solve many of the QoV problems that degrade low contrast VA and night vision performance under low light conditions after refractive surgery. However, there is still much to learn about higher order aberrations, and particularly their role in visual performance and how to adjust for them with refractive surgery. Until that time, however, the USAF must continue to monitor QoV issues after PRK and remain intensely vigilant regarding RS procedures. The bottom line is that any reduction in mesopic night vision or NVG visual performance could have a disastrous effect on the ability to maintain a safe and effective night fighting force in what is evolving to be an increasingly large number of post-refractive surgery military aviators.

In summary, it is unequivocal that increased optical aberrations and light scatter are present in some patients before and after refractive surgery, including PRK, especially in the more peripheral regions of the cornea. Therefore, it is essential that post-PRK patients be comprehensively tested under mesopic adaptation conditions that allow pupillary dilation. Accordingly, this study was designed to evaluate post-PRK changes under three mesopic night vision scenarios: (1) low contrast vision under mesopic light levels; (2) mesopic contrast sensitivity with and without glare; (3) NVG visual acuity under two ambient lighting conditions. Specifically, the Rabin Small Letter Low Contrast Chart was used to measure small letter contrast sensitivity at mesopic light levels. The Mesotest II b model (Oculus, Germany) mesoptometer was used to evaluate low contrast mesopic vision both with and without glare. NVG acuity was accessed under quarter moonlight and starlight using a new G-model AN/AVS-9. These three parameters of mesopic night vision were chosen because of their direct correlation to operational lighting situations. The evaluations were conducted over 24 month duration to provide fairly long-term post-PRK data, and a broad sample of carefully selected subjects was utilized that met all USAF Flying Class III vision standards. Finally, it should be

noted that this study was simply intended to be an initial evaluation of QoV issues post-PRK; and, it had certain design constraints and resource limitations. It was designed to be a 12- 24 months post-PRK selection study and not a return-to-cockpit study. It was also expected at the time that follow-on studies would be done to further refine any issues missed or identified to be potential issues in this initial study.

PURPOSE

The purpose of this study was to evaluate mesopic and night visual performance before and after photorefractive keratectomy (PRK) in terms of low light mesopic visual acuity, mesopic contrast sensitivity with and without glare, and resolution with night vision goggles. The primary goal was to detect and identify any changes in mesopic and/or NVG visual function, which may have been induced by PRK surgery or its sequela, which could negatively affect operational night flying. An additional goal was to determine if new aeromedical vision standards were needed for USAF aviator applicants that had experienced PRK surgery. Accordingly, a prospective experimental design was used to evaluate a subject population, carefully selected to match the visual attributes of USAF pilots, over a longitudinal time period extending from baseline (pre-PRK) to 24 months post-PRK. It should be noted that this was only intended to be a preliminary study designed to support selection policy for aviation candidates who had undergone PRK; and, it was not optimized as a return-to-fly study following PRK. As such, follow-on studies were planned as part of a larger research program to more thoroughly evaluate the efficacy of PRK, and all refractive surgeries, for potential adoption into USAF aviation and aeromedical policy.

METHODS

Subjects

One hundred non-flying active duty USAF personnel volunteered to be subjects for this prospective mesopic night vision and NVG study and to undergo PRK corneal refractive surgery. As part of the selection process, all subjects were required to undergo a full-dilated ocular examination and comprehensive vision screening in the Ophthalmology Branch, Aeromedical Consultation Service, USAF School of Aerospace Medicine, Brooks AFB TX. Aeromedical vision standards for Flying Class III were applied per Air Force Instruction 48-123, Aerospace Medicine: Medical Examinations and Standards, as the primary criteria for subject selection. Additionally, all subjects had to pass vigorous pre-surgical criteria and receive official approval to proceed with the PRK procedure. All pre- and post-operative visual and physiological function testing was conducted at Brooks AFB TX per the study protocol as approved by the Brooks Institutional Review Board (IRB #98-F-BR-0016-H). All PRK surgery was performed at the Laser Refractive Surgery Center in the Ophthalmology Department at Wilford Hall Medical Center, Lackland AFB TX, per the approved surgical protocol IRB- SGO # 95-183 as revised on 25 Mar 97. Voluntary informed consent was obtained on all subjects as required in the protocols and AFI 40-402. Specific selection criteria and subject demographics are provided in companion publications to be sequentially published.

Of the subjects selected, twenty were used as controls and eighty were chosen to receive PRK treatment. The subjects were initially screened for selection by means of an extensive preoperative work-up and a lengthy questionnaire, which served to eliminate subjects with contraindications for PRK in accordance with established FDA study criteria. After making the final cut, a total of 80 patients or 160 eyes were evaluated and followed after treatment within the USAF PRK Study protocol. All PRK surgical procedures were performed by a single surgeon at Wilford Hall Medical Center using a VISX Star (VISX, Inc., Santa Clara CA), 193 nanometer, argon fluoride (ArF) broad-beam excimer laser (23). The magnitude of refractive errors treated in the study, based on cycloplegic examinations and spherical equivalent values, showed pre-surgical mean values of -3.28 (+/-1.49) diopters for the right eye, and -3.23 (+/-1.47) diopters for the left eye. The range of pre-surgical refractive errors was -1.00 to -6.38 diopters for the right eye, and -1.00 to -6.63 diopters for the left eye.

The treated group was further divided into four sub-groupings of twenty subjects each for operational laboratory tests, which were required for other segments of the comprehensive PRK study. These four separate study groups were created within the treated subject pool to evaluate post-PRK effects on simulated operational performance. The four study groups were: (1) human centrifuge study group; (2) altitude chamber study group; (3) simulated cockpit environment study group; (4) a treated control group that did not participate in any laboratory performance testing. Because the laboratory tests required exposure to centrifugal forces, or high altitudes, or bright glare light or laser sources, the mesopic night and NVG testing was always completed before these tests were run. Accordingly, these sub-groups were not used as statistical variables in this study since there was no direct relationship to the mesopic night and NVG testing. The group data from the operational performance testing in the individual laboratory subsets is reported in companion USAFSAM Technical Reports in this series (26).

This prospective study required data collection on subjects at regular intervals. Initial readings were accomplished to obtain baseline values and subsequently at set intervals over a 24 month time period post-PRK surgery, or post-baseline reading for untreated controls. Limitations in the surgical schedule precluded doing all the PRK surgeries at the same time; in addition, some subjects had their right and left eyes treated several months apart. As a consequence, a total of 42 months was required to complete the data collection on all subjects.

As mentioned, this mesopic night and NVG visual acuity segment was part of a much larger evaluation of post-PRK visual performance that included many other performance tests, both visual and operational. Because of the lengthy experimental follow-up schedule, USAF personnel actions, and the requirement for many of the subjects to continue to participate in uncomfortable laboratory tests, e.g., rides in the human centrifuge, ascents in the altitude chamber, or testing in the F-16 simulator with bright laser glare, some subjects did not complete all follow-up exams. This attrition prevented consistency in the number of subjects, or eyes, seen at each of the follow-up points for statistical analysis, so that the total subject count differed for each session. Also, it should be noted that the monocular and binocular data sometimes varied in number because some subjects had their right and left eyes treated more than four months apart. Obviously, this precluded having binocular test data at the first follow-up visit for everyone. In addition, not all testing was conducted at the four-month follow-up evaluation because of patient schedules and time constraints, especially since most study subjects were required to participate

in lengthy testing in the human centrifuge, altitude chamber, or F-16 simulator. Tests that were not performed at the four-month follow-up included all mesoptometer testing and the NVG trials with the USAF High/Low Contrast NVG Resolution Charts. In hindsight, this was considered an oversight in a selection based study because that data would have been valuable in developing return-to-cockpit criteria after PRK.

Mesopic Low Contrast Vision Testing

The measurement of mesopic low contrast vision was accomplished by using two different tests. One, the Small Letter Contrast Test (SLCT) chart (54), provided a measure of low contrast VA under mesopic lighting conditions for a high spatial frequency target. The other, the Mesotest II b mesoptometer testing device (55), provided a measure of mesopic low contrast performance, without and with glare, for a low spatial frequency target. Merging the data from subjects for these two tests provided a more comprehensive range of mesopic night visual function.

The SLCT chart, shown in Figure 2, was designed by a US Army vision scientist (54) to provide a sensitive measure of visual capabilities in applicants for military aviation, especially those candidates that had undergone refractive surgery. The Rabin SLCT measures visual performance at one letter size, or spatial frequency, across a wide range of contrast levels. The letter size is equivalent to 20/25 Snellen VA; the detail in each letter subtends 1.25 minutes of arc at the testing distance of 4 meters. The chart consists of 14 lines of letters with 10 letters per line. Each successive line going down the chart uniformly decreases in contrast by 0.1 Log units and increases in contrast sensitivity (CS) by 0.1 Log CS steps. Accordingly, each letter is equivalent to 0.01 Log CS. The scores for number of letters correct can be easily converted to relative log contrast sensitivity values by multiplying by 0.01 and then subtracting 0.1, e.g. a score of 63 letters correct is equivalent to 0.53 Log CS. Lighting for the SLCT chart was maintained at a mesopic value of 3.8 Cd/m^2 (1.1 fL). Testing was conducted at each session using a trial frame with best spectacle correction and measuring, using standardized forms, the actual number of letters read to obtain a small letter contrast acuity score for OD, OS, and OU. Data collection was performed at baseline (or pre-PRK) and at 4, 6, 12, and 24 months post-baseline, and subsequently input to a computerized database for statistical work-up

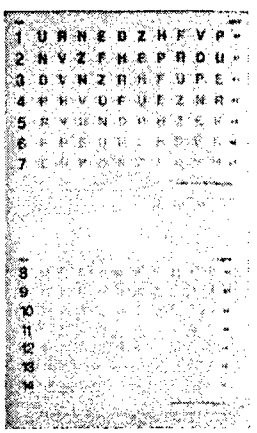


Figure 2. Rabin Small Letter Contrast Test (SLCT) Chart.

The Mesotest II b (Oculus Ophthalmic Instruments, Germany), as shown in Figure 3, was the test device of choice for measuring some additional parameters of mesopic vision. The Mesotest II b is the newest generation mesoptometer and it incorporates an advanced electronic control system to make it more streamlined, lighter, and mobile than earlier versions (55). This device is used as a clinical screening test for mesopic vision under conditions of low contrast and glare. Currently it is recommended by the German Ophthalmological Society as a primary night vision screener to test drivers for private and/or commercial vehicle licenses (14, 32). The Mesotest II b has great utility as a standardized instrument for night vision research studies because it provides a quantifiable performance measure of night/mesopic visual function both with and without glare. The brightness of the test surround, which is 0.032 Cd/m^2 (0.01 fL) without glare and 0.10 Cd/m^2 (0.03 fL) with glare, corresponds to the ambient brightness of automobile traffic at twilight or at night. The glare source, which is a pinpoint light of 0.35 lux brightness at an angle of three degrees to the left of fixation, simulates an approaching car at night with its headlights on low beam brightness.

The Mesotest II b presents a virtual image that is optically calibrated to provide an equivalent testing distance of 5 meters. It employs 2 white LEDs, one to light the test surround, and the other to function as the glare source. Standard Landolt C rings (DIN Norm # 58220-T1) that have a constant gap size equating to 20/200 Snellen visual acuity, or 3 cycles per degree, are used as optotypes (Fig.3). During testing, the Landolt rings can be selectively presented at four different contrasts and 6 different orientations. A total of eight test positions are run successively in the testing routine; tests # 1-4 are done without glare and tests # 5-8 are done with the glare source on. Tests # 5-8 are presented at the same 4 contrast levels as tests # 1-4, but in brighter surround light because of the brightness of the glare source employed. The four contrast ratios preset in this test device were, in order of presentation, 1:23, 1:5, 1:2.7, and 1:2, which corresponds to contrast values of 92%, 67%, 46%, and 33% respectively in terms of Michelson contrast (Weber contrast values were 98%, 80%, 63%, and 50% respectively).

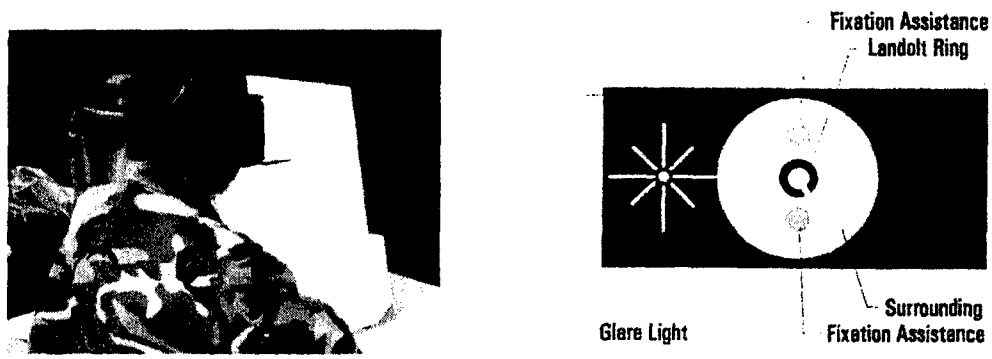


Figure 3. Mesotest II b tester (left) and schematic of the Landolt Ring optotype (right) as viewed by the subject.

Testing was uniformly standardized by running the Mesotest II b in a completely darkened room and dark-adapting all subjects for at least 10 minutes before beginning the test session. A trial frame was fitted on each subject with lenses based on the subject's current manifest refraction to provide best corrected VA. If no Rx was required, plano lenses (no power) were placed in the

trial frame. The testing protocol required an initial non-scored trial with feedback, as to which of the 8 possible orientations the gap was in, before subjects were presented the 5 trials to be scored. To receive credit for passing each test, subjects were required to correctly identify the orientation of the Landolt C on at least 3 out of the 5 trials. According to binomial probability calculations, there is only a 3.2% possibility of correctly identifying 3 of 5 presentations by chance. A pass or fail score was recorded for each of the tests # 1-8. The sequence of testing was always OD, OS, and OU without glare, and OD, OS, and OU with glare.

Night Vision Goggle Testing

A F4949G (AN/AVS-9) model NVG (serial number 6910, ITT, Roanoke VA) was used in this study and a similar version is depicted in Figure 4. It was purchased specifically for this study and used throughout the entire 42-month time period without being used for any other purpose. A second identical F4949G model was purchased at the same time to provide backup, but it was not needed. This model comes equipped from the manufacturer with a NVIS Class B with Leaky Green (a.k.a. Class C) filter for compatibility with blue-green cockpit lighting (Figure 5). Preliminary in-house evaluation revealed that this particular NVG had the capability to provide excellent visual acuity. The 20/30 grating pattern on the USAF High Contrast NVG Resolution Chart could be readily resolved under quarter moon illumination by most subjects under binocular viewing conditions. This was in good agreement with previous reports in the literature for studies (36-38) using a similar grating eyechart and a F4949G model NVG. Resources and time requirements to conduct this study did not allow a comprehensive assessment of all potential NVG operational scenarios; accordingly, quarter-moon and starlight illumination were chosen for the testing because they provided a realistic operational range of ambient lighting levels.

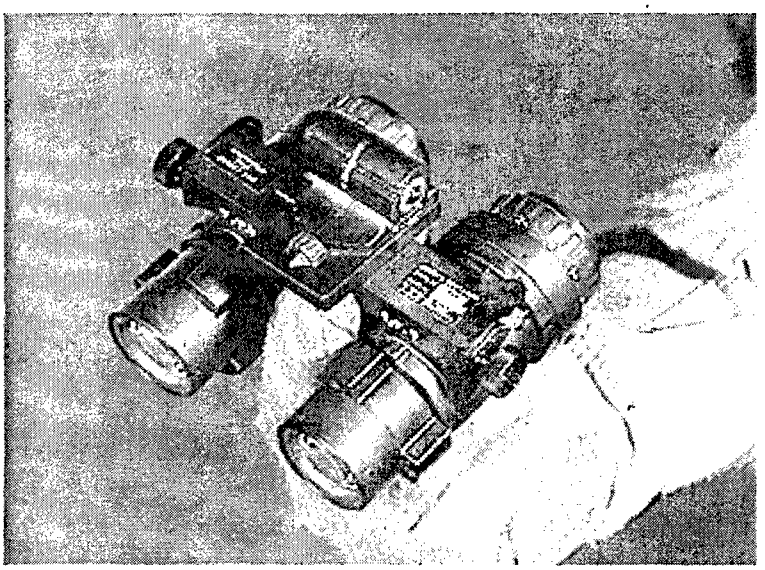


Figure 4. F4949G model NVG (AN/AVS-9).

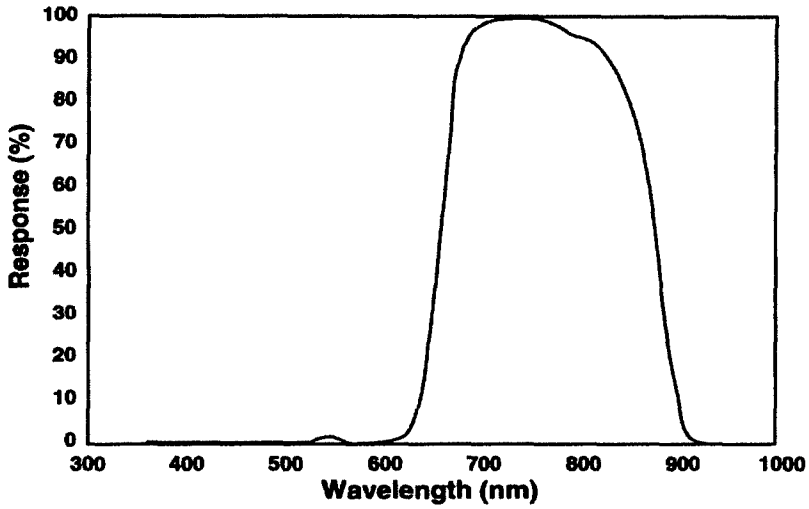


Figure 5. Sensitivity Response of the Class B Filter with Leaky Green.

Most subjects had no prior experience viewing through NVGs, so a standardized demonstration of NVG adjustment procedures and overall function was provided for each subject before every scheduled test session to ensure uniformity of training. Controls and treated subjects alike completed the same battery of NVG visual acuity tests (described below) at "baseline", and 4, 6, 12, and 24 months later. A scatter plot of NVG visual acuity in untreated subjects (controls) over time was prepared to track any fluctuation in the gain of the NVG electro-optical system (intensifier tube) performance during the study. As shown in the Results and Discussion Section, the NVG tubes used in this study were very stable over the 42-month time period. An insignificant change in mean VA was found over this time period, which amounted to a loss of about 0.5 letters per tube per year.

A commercially available LM-33-80A Variable Night Sky Projection System (Hoffman Engineering, Stamford, CT) was used to illuminate the NVG visual acuity test charts. The Night Sky Projector is the military standard for research and operational NVG testing. It provides a series of set light levels that simulates typical concentrations of night sky energy. Its quartz-halogen light source is filtered to mimic the spectral distribution of infrared and visible light as normally found in the night sky, which approximates the spectral sensitivity of the gallium arsenide sensor in the NVG image intensifier tube. The desired lighting level was obtained by turning the switch to the appropriate ambient lighting position, e.g., quarter moon, starlight, etc., and by adjusting the aperture setting. Constant chart luminance levels were maintained by setting the Night Sky Projector switch to the desired position and correct aperture setting, fine-tuning the distance to the VA chart, and altering the projection angle as needed. Calibration was conducted by using a PR-1530 Photometer and Radiometer (Photo Research, Chatsworth, CA) to measure several symmetrical locations scattered over the white portion of the NVG resolution and Bailey-Lovie charts (Figure 6). The projector was always positioned so that the quarter moon setting measured 5.6×10^{-10} Watts cm^{-2} $Steredian^{-1}$ in NVIS radiance units (weighted for the spectral response of the NVGs) on the selected positions of the eyecharts. The equivalent photopic luminance was measured as 0.001 Cd/m^2 (0.0003 fL) with a Pritchard PR 1980A. The starlight setting on the Night Sky Projector was similarly measured and calibrated to read 1.6×10^{-10} Watts cm^{-2} $Steredian^{-1}$ in NVIS units, or 0.0001 Cd/m^2 photopically. Chart radiance was

monitored periodically over the course of the study and showed good stability. Preliminary testing in our Night Vision Laboratory suggested that NVG visual acuity remained essentially unchanged with minor fluctuations in chart illumination levels up to as much as 15%. The output luminance of the NVGs as viewed by the observer was measured to be 3.8 Cd/m^2 (1.1 fL) for the quarter moon setting and 1.0 Cd/m^2 (0.3 fL) for the starlight setting, which is in the upper mesopic range.

To provide the best range of operational relevance for the NVG visual acuity testing, three eyecharts (Figure 6) were chosen: (1) a USAF High Contrast NVG Resolution Chart; (2) a USAF Low Contrast NVG Resolution Chart; (3) a commercially available high contrast Bailey-Lovie chart.

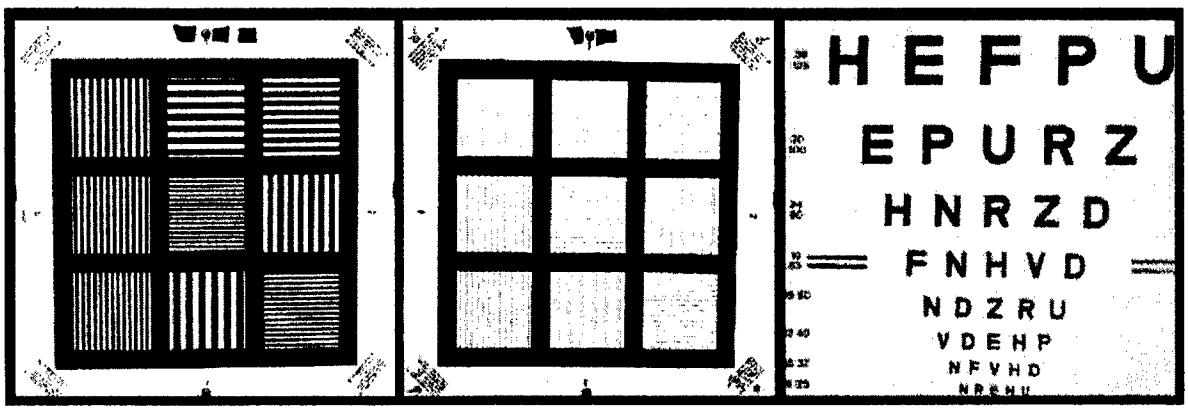


Figure 6. Visual acuity charts used for NVG testing. From left to right: High Contrast NVG Resolution Chart of square wave grating acuity ranging from 20/60 to 20/20; Low Contrast NVG Resolution Chart of grating acuity ranging from 20/100 to 20/35; Bailey-Lovie letter eyechart with VA ranging from 20/125 to 20/6.3.

The High and Low Contrast NVG Resolution charts consist of nine grids, or square wave gratings, in a 3 by 3 matrix design with a range of spatial frequencies. The individual gratings on the High Contrast NVG Resolution chart range from 10 to 30 cycles per degree, which corresponds to an equivalent Snellen range from 20/60 to 20/20. A spatial frequency of 30 cycles/degree is used as a reference in non-NVG studies because it is considered to be the equivalent of 20/20 Snellen VA. Spatial frequency in cycles per degree can be easily calculated as follows: the detail of a 20/20 letter subtends 1 minute of arc, so a cycle, which is one light bar plus one dark bar, would be 2 x 1 minute of arc, and 2 goes into 60 minutes (1 degree) a total of 30 times. A useful rule of thumb to convert to spatial frequency is to take the denominator in the Snellen fraction (20/x) and divide it into 600 to obtain cycles/degree, e.g., a 20/30 letter or optotype would be equivalent to 600/30 = 20 cycles/degree, a 20/100 optotype would be equivalent to 600/100 = 6 cycles/degree, etc. Scoring for the USAF High and Low Contrast NVG Resolution Charts are based on correct responses to the orientation of the gratings, which are either vertical or horizontal. The charts can be rotated to four different positions to provide more alternatives and prevent memorization.

The USAF High Contrast NVG Resolution Chart has played a prominent role in previous research studies (36-40) and it is the standard chart used by aviators at many operational USAF bases for pre-flight focusing and adjustment. Once this chart was implemented for operational preflight focusing, visual performance improved significantly over previous preflight methods (38). Accordingly, the chart was used in this study for pre-test adjustment and focusing prior to each data collection session as well as being one of the eyecharts used to measure VA with NVGs. The relative contrast of this chart was measured, using the Michelson contrast equation, as 97% in room light (photopic) and 76% when measured through the NVGs with quarter moon illumination. For testing with the USAF High Contrast NVG Resolution Chart, quarter moon illumination was used to provide a measure of performance at the upper range of operational ambient conditions.

The companion USAF Low Contrast NVG Resolution Chart was also used as a test chart for this study. It is analogous to the high contrast chart except it has low contrast square wave gratings with a Snellen equivalent acuity range from 20/100 to 20/35. The Low Contrast chart was measured as having a Michelson contrast of 30% when measured photopically and 16% contrast measured through the NVGs when viewed in starlight room illumination. Testing with this low contrast chart was done only under starlight illumination in an effort to obtain a measure of VA at the lower limit of probable ambient conditions for NVG operational use.

Although the NVG Resolution charts provide an excellent target for NVG pre-flight testing and adjustment procedures, the use of these charts to precisely measure and accurately quantify VA has not been universally accepted. This is because testing NVG visual acuity with sine wave grating charts has some inherent problems. First, the phenomenon of frequency doubling can often incorrectly inflate VA scores, especially at the critically important high spatial frequency end. Second, there is a 50% chance of subjects guessing correctly for any size of grating, since there are only two choices for orientation (vertical or horizontal). Third, resolving grating patterns requires detection instead of discrimination; therefore, the equivalent Snellen fraction used for gratings does not exactly correspond to the Snellen fraction on a letter eyechart. Fourth, spatial frequencies and grating patterns are more difficult for non-scientists to understand than letters and Snellen VA fractions. Therefore, the principal eyechart that was used in the NVG testing was the Bailey-Lovie (B-L) letter chart.

The B-L chart used in this study was a commercially available high contrast (97% Michelson) letter chart that compares favorably with other commonly used eyecharts including the ETDRS, Regan, Precision Vision, etc. (55). It is a well-designed logarithmically scaled letter eyechart that provides visual acuity in terms of LogMAR, which has become the gold standard for VA measurements in general (56). It is designed to provide the logarithm of the minimum angle of resolution (LogMAR) using five letters per line and equal (0.10 LogMAR) steps between lines. Acuity was measured by counting the actual number of letters correctly read and calculating the LogMAR, i.e., the number of letters correctly read is directly proportional to LogMAR VA. NVG testing with this chart was always conducted using quarter moon room illumination. Scoring the Bailey-Lovie letter chart required a count of the total number of letters correctly read for OD, OS, and OU. The number of letters correct is directly proportional to LogMAR and can be easily converted to Snellen acuity by a standard equation: Snellen VA = 20*[10^ 0.9-(0.02*# Correct)]. For example, at a test distance of 20 feet, reading 30 letters correct is equal to a

LogMAR of 0.30 which computes to 20/40 Snellen. LogMAR values, calculated from the number of letters correct, were used for all computations and statistical analyses and eventually converted to Snellen VA for graphical display.

Finally, some factors used in the methodology must be defined. First, all NVG testing was conducted with subjects wearing their best spectacle correction in a trial frame (even optical prescriptions of low power). No uncorrected NVG data was collected on post-PRK subjects because the original experimental design intended this to be a preliminary study oriented toward comparison with best corrected visual performance in order to determine the "PRK effect" from an aircrew selection perspective. As stated earlier, this initial PRK study was not designed as a return to cockpit assessment for trained aviators. Follow-on studies were planned to evaluate several other aspects including uncorrected NVG acuity. Obviously, uncorrected post-PRK data has great value for quantifying NVG visual performance under realistic operational conditions and would be more appropriate in a return to cockpit study for trained aircrew. That is because it is very unlikely that post-PRK aviators will want to wear minor or even moderate optical corrections when performing flying duties. Second, the design of the study was not focused on initial recovery but more on long term stability. Accordingly, little data was collected prior to 6 months post-PRK or post-baseline. The only NVG data collected at 4 months post- PRK was on the Bailey-Lovie chart, and no data was collected with the two NVG grating charts at 4 months. Obviously, four month data is important because physiological healing effects, e.g., corneal haze, microcystic edema, desiccation, etc., are more likely to be present early on. However, the study design combined with realities of subject schedules and time constraints dictated reducing overall testing time. Accordingly, the Bailey-Lovie chart was selected as the principal eyechart for this NVG study due to its inherent advantages over grid charts as discussed above; and, it's greater prominence is also reflected in the statistical analysis. Third, monocular data from the control group was used to detect any drop-off in performance of either NVG intensifier tube over time. As shown in the Analysis of NVG Visual Acuity Data Section, performance with the right and left image intensifier tubes was relatively consistent over time and essentially equal.

Data Collection and Analysis

All mesopic and NVG testing was conducted in the Night Vision Laboratory of the Aerospace Vision Section, Ophthalmology Branch, Clinical Sciences Division, USAF School of Aerospace Medicine (USAFSAM/FECO), Brooks AFB TX. To maintain dark adaptation, the order of testing was always: (1) Rabin SLCT chart; (2) NVG test charts; (3) Mesoptometer measurements. Standardized instructions were given to each subject on exactly how to respond to each type of test system for all the conditions. The subjects were required to dark adapt to a luminance of 3.8 Cd/m^2 for 5 to 10 minutes. Mesopic night vision was subsequently tested using the Rabin SLCT chart, which was also at a luminance of 3.8 Cd/m^2. This usually took an additional 10 minutes from start to finish and resulted in each subject being dark adapted to low mesopic levels for at least 15 minutes before the NVG testing started. As previously reported, the NVG testing was conducted in sequence with starlight illumination initially tested and then quarter moon so as to maintain dark adaptation. The mesoptometer tests were then run to complete each testing session, with the glare part of the testing done last. A standardized paradigm required the ocular order for all VA testing to be right eye (OD) first, left eye (OS)

next, and finally both eyes together (OU). Obviously, the corresponding order for testing with the NVGs was right image intensifier tube, left tube, and both tubes together.

Testing was designed so that the NVG was positioned on a standard NVG mount which was permanently fixed to a head and chin rest. Electrical power was provided by a custom designed AC to DC converter that supplied a constant source of electricity without fluctuation. The subject was positioned at a distance of 20 feet from the VA charts and the Night Sky Projector was positioned on the floor between the subject and chart so as to not interfere with their NVG viewing line of sight. Before each testing session began, a staff member calibrated proper chart luminance using a PR-1530 Spectroradiometer that measured NVIS (Night Vision Imaging System) radiance, pre-focused the NVG objective lenses, and confirmed chart resolution. The NVG was adjusted individually for each subject for eye height, alignment, and interpupillary distance. Subjects were instructed on proper focusing procedures for the dioptric focusing knobs (oculars) of each eyepiece. Subjects were not allowed to focus the objective lenses so that the same pre-focused setting remained in place throughout the test session.

The NVG testing commenced with the 3 VA charts, and the illumination used, in the following order: (1) USAF Low Contrast NVG Resolution Chart under starlight illumination; (2) USAF High Contrast NVG Resolution Chart under quarter moon illumination; (3) Bailey-Lovie eyechart under quarter moon illumination. For the NVG grating charts, subjects had to indicate whether each grid pattern was oriented horizontally or vertically. After the subjects responded to all nine grid patterns, the chart was rotated and subjects again indicated the orientation of each of the nine patterns. This was repeated for a total of eight times and subject responses were recorded each time on 3 by 3 matrix score sheets. The NVG Bailey-Lovie VA chart test for letter VA was presented using the same testing order of OD, OS, and OU. The actual number of letters correctly identified was scored and recorded. Laboratory design included a microphone, television monitor with input from a NVG camera, and video recorder to monitor and record observer responses from an adjacent light tight room. Accordingly, videotape was produced for each subject, which was used for analysis later to check the hand scored data. Total NVG testing time was typically 30 minutes per subject. Bailey-Lovie chart acuities were collected at baseline, 4, 6, 12, and 24 months post-PRK surgery and at equivalent points for controls post-baseline. Performance on the USAF High and Low Contrast NVG Resolution Charts was also measured at the same times except not at the four-month follow-up session.

The procedure for evaluating monocular results was to analyze the right and left eyes separately for the Rabin SLCT chart and mesoptometer data. Data between eyes is correlated on most ocular tests and, if data were pooled, a correction for intraclass correlation between eyes would be necessary (57, 58). Otherwise, statistical significance from analysis might be inflated by an amount proportional to that correlation. For the NVG testing, however, right and left eye data was pooled because we are really measuring each eye/image intensifier tube as a system. Each NVG image intensifier tube has its own unique idiosyncrasies, which vary within specific tolerances based on military and engineering specifications, and each eye views a similar, but different, tube/phosphor screen system. More importantly, each image intensifier tube requires independent focusing of two mechanisms, the objective and the eyepiece (dioptric) lenses, to obtain the clearest image for each eye/tube system, which further increases their independence. Therefore, some of the NVG monocular data was pooled for analysis.

Visual acuity testing on the Bailey-Lovie eyechart with NVGs was measured by counting the number of letters correct and recorded using standard clinical practices (56, 59, 60). Scoring for the USAF High/Low Contrast NVG Resolution Charts was computed as a threshold value from the total number of responses out of the eight trials that correctly identified the pattern as horizontal or vertical for each of the nine spatial frequencies. Threshold was defined as 75% frequency of seeing (6 out of 8) and analyzed with a best-fit curve from the Table Curve 2D, v5.01; SYSTAT Software Inc. Figure 7 displays the frequency of seeing curve graphically for a typical subject; and, it illustrates how the threshold values were extrapolated. This graph shows a very characteristic curve where the larger grating patterns were usually seen 100% of the time but the smaller grating patterns were seen less than 50% of the time. Each grating pattern had a specific spatial frequency value that corresponded to the number of cycles per degree of visual angle that it subtended at the 20 foot testing distance. Spatial frequencies were converted to corresponding LogMAR values, which were used for all calculations, and then converted to equivalent Snellen by the equation: Snellen VA = 20*(10^LogMAR). Although inherent and significant differences exist between Snellen letter VA and grating patterns (61, 62) conversion to Snellen values provides a rough order of magnitude comparison and greatly simplifies operational and clinical use of the NVG Resolution Charts.

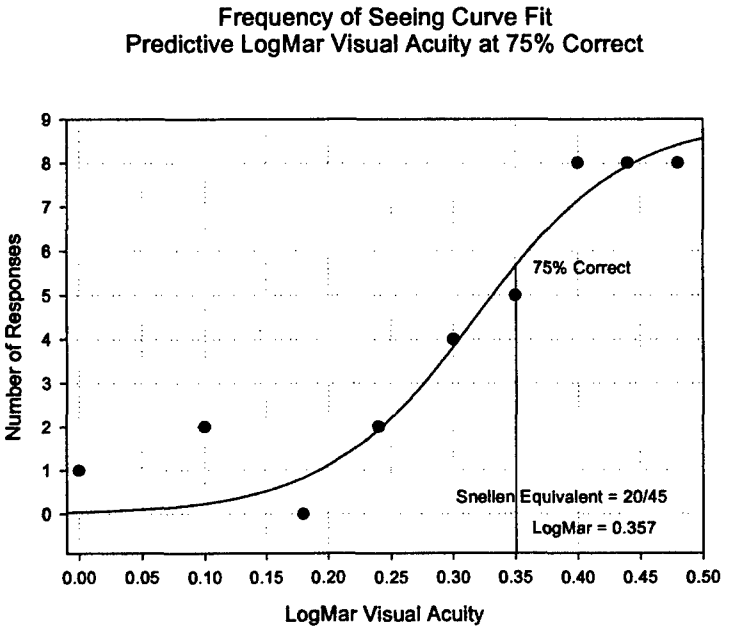


Figure 7. Frequency of seeing curve for the NVG grid chart fit for a typical subject. Data points are the number of times, out of 8 trials, that each of the 9 grid patterns (in LogMAR units) were correctly identified as horizontal or vertical. The threshold value is extrapolated from the 75% frequency of seeing point.

Finally, some analyses of the visual performance data after PRK were conducted by comparison with previously established arbitrary aeromedical criteria, e.g. 20/50 monocular NVG visual acuity, which is the recommended criteria for minimal operational performance with NVGs, as found in Air Force Instruction 48-123, Aerospace Medicine: Medical Examinations and

Standards. While not officially established as a NVG vision standard, 20/50 is considered to be easily achievable with current NVGs on high contrast charts and is used as an operational indication of minimum expected performance. Aircrews unable to achieve at least 20/50 vision with NVGs are directed for ocular examination to determine the cause. In fact, the NVGs used in this study should routinely allow for NVG acuity better than 20/30. It is unequivocal that mesopic night vision and NVG-aided mesopic visual acuity play a critical role in modern night combat missions. Real changes in any aspect of night mesopic vision, and subtle quality of vision issues that are difficult to detect, may impact performance. Consistent complaints have been reported in the literature about reduced quality of vision after PRK, especially at night and particularly under conditions of glare, despite the presence of better than 20/20 vision on a standard Snellen eyechart. In addition, instances occurred where there may not have been statistically significant group findings, but aeromedical clinical criteria revealed that some individual differences were potentially operationally relevant. Also, statistically significant correlations may not have been found with some data, but a trend could be identified that had possible operational relevance and warranted further analysis. Therefore, a multifactoral approach was employed using statistical and aeromedical criteria to subjectively assess operational relevance post-PRK and the potential impact on returning a pilot to full flying status.

RESULTS AND DISCUSSION

Analysis of Rabin Small Letter Contrast Test Data

Tables 1-3 display the mesopic Rabin SLCT data in terms of number of letters read correctly. Statistical analysis was performed using units of Log CS (63); but, the data were displayed in a more understandable format as number of letters read correctly. The Rabin SLCT data collected under this experimental protocol included: (1) uncorrected (without optical correction) values at 4, 6, 12, and 24 months post-PRK compared to pre-PRK baselines with best spectacle correction in a trial frame; (2) corrected (with best optical correction) values at 4, 6, 12, and 24 months post-PRK compared to pre-PRK baselines with best spectacle correction in a trial frame. Table 1 provides the data for the control group, i.e., no PRK surgery, collected over time with their best spectacle correction. The data reveal a slight, and statistically insignificant, increase in performance over time based on the number of letters that can be correctly read at each of the post-baseline times compared to initial baseline values. This small increase may reflect learning or a training effect which is not surprising for threshold testing in dim light. The possibility of a training effect is also supported by the decrease in standard deviation (SD) values over time.

Table 1. Means and Standard Deviations for the control group (no PRK) based on the number of letters correctly read on the Rabin SLCT under mesopic lighting. Baseline means and the 4, 6, 12, and 24 months post-baseline data were determined with best spectacle correction in a trial frame (Corrected). No statistically significant differences existed at any post-baseline evaluation time compared to baseline values using Bonferroni Post Hoc Analysis.

	No PRK	No PRK (post-baseline)			
	Baseline Corrected (N=20)	*4 Months* Corrected (N=18)	*6 Months* Corrected (N=16)	*12 Months* Corrected (N=18)	*24 Months* Corrected N=17)
OD	51.4 +/-15.1	55.8 +/-11.8	56.4 +/-13.3	52.9 +/-12.7	53.4 +/-10.0
OS	52.6 +/-16.5	58.5 +/-9.3	59.4 +/-9.8	58.1 +/-13.3	53.4 +/-10.1
OU	63.0 +/-13.5	69.8 +/-9.2	68.7 +/-9.2	64.6 +/-11.2	61.2 +/-9.5

Statistical analysis of the Rabin SLCT data for treated subjects measured post-PRK without correction revealed that there were very significant differences from pre-PRK baselines. As seen in Table 2, the mean number of letters read correctly is decreased at all times for post-PRK visual performance in subjects tested without correction as compared to trial frame best corrected pre-PRK baselines for OD, OS, and OU. Also, the standard deviations (SDs) show increased variability/variance post-PRK compared to baselines. This trend runs counter to the general drift towards better performance and decreased variance over time found with repeated measures in the control group. Not all subjects were tested post-PRK without correction because of study time constraints and subject schedules. Consequently, the number of subjects, or N value, varies at each evaluation time.

Table 2. Means and Standard Deviations for PRK treated subjects based on the number of letters correctly read on the Rabin SLCT under mesopic lighting. The pre-PRK baseline means were determined with best spectacle correction in a trial frame (Corrected), while the 4, 6, 12, and 24 months post-PRK data were collected with no correction (Uncorrected). Statistical significance was determined for each post-PRK evaluation time by comparing to baseline values using Bonferroni Post Hoc Analysis. Significance denoted as (*) at .05, and (**) at .005.

	No PRK	Post-PRK			
	Baseline Corrected N=79	*4 Months* Uncorrected N=36	*6 Months* Uncorrected N=48	*12 Months* Uncorrected N=62	*24 Months* Uncorrected N=57
OD	45.3 +/-18.1	33.3** +/-22.7	34.4* +/-21.0	33.9* +/-22.8	38.5* +/-21.9
OS	49.0 +/-17.5	27.9* +/-22.7	35.9v +/-23.2	33.0* +/-21.5	35.2* +/-20.5
OU	62.0 +/-16.7	46.0** +/-22.6	46.6* +/-22.5	47.2** +/-21.4	52.2* +/-17.2

Table 3 displays the data for the treated subjects tested post-PRK with correction (best spectacle correction in a trial frame). Statistical analysis of these post-PRK corrected data revealed that there were no significant differences between pre- and post-PRK test results at any follow-up time. Like in the control group, a statistically insignificant trend can be observed toward improved performance, i.e., being able to detect more letters or having enhanced contrast sensitivity post-PRK. Although this may have been partially due to a learning effect; a plausible explanation is that the slight increase in performance represents a real improvement post-PRK in resolution of small letters at low contrast. Optically, there may be an enhancement effect as a result of the relative magnification (or lack of spectacle minification) in the retinal image post-PRK, compared to the minified image presented with spectacles pre-PRK. It has been reported that the magnification effect is intensified with small letter low contrast types of eyecharts, or CS function tests, as compared to standard high contrast Snellen letter eyecharts (54). The predicted change in VA or CS resulting from correction at the corneal plane can be calculated and quantified. For example, a -4D myopic patient corrected with spectacles to emmetropia, compared with PRK surgical correction to emmetropia, is expected to show an improvement of 0.02 log MAR (1 letter) on high contrast VA tests. As mentioned, a greater effect with low contrast charts, e.g., the CS Rabin SLCT chart, can be anticipated that is probably closer to 1 line (10 letters) or 0.1 log CS (54, 64). Therefore, a small beneficial effect from PRK correction in myopes, due to the increased relative magnification in the retinal image at the corneal plane, should be expected when comparing their post-PRK VA or CS to their best-corrected pre-PRK performance. However, absolute differences from the baseline data equated to a real improvement of only a few letters post-PRK, which were not statistically significant.

Table 3. Means and Standard Deviations for the number of letters correctly read on the Rabin SLCT under mesopic conditions for PRK treated subjects. Baseline means were determined with best spectacle correction in a trial frame (Corrected), as was the 4, 6, 12, and 24 months post-PRK data. No statistically significant differences were found at any post-PRK evaluation time compared to baseline values using Bonferroni Post Hoc Analysis.

	Pre-PRK	Post-PRK			
	Baseline **Corrected (N=79)**	***4 Months*** **Corrected (N=70)**	***6 Months*** **Corrected (N=74)**	***12 Months*** **Corrected (N=71)**	***24 Months*** **Corrected N=56)**
OD	**45.3 +/-18.1**	**48.0 +/-19.7**	**48.4 +/-18.2**	**51.6 +/-16.0**	**48.9 +/-14.5**
OS	**49.0 +/-17.5**	**50.9 +/-16.7**	**53.5 +/-15.6**	**52.8 +/-16.0**	**50.4 +/-17.4**
OU	**62.0 +/-16.7**	**63.6 +/-16.3**	**63.9 +/-14.8**	**63.7 +/-12.4**	**62.6 +/-11.0**

Another way to evaluate the data is to compare post-PRK performance to an arbitrary baseline value, or typical clinical standard, e.g. 2 SDs below the mean of a large database, and establish pass/fail criteria. Accordingly, pass/fail criteria were derived by combining the baseline data for all 99 subjects, both controls and treated (1 subject withdrew after treatment), and calculating the appropriate means and SDs. Mean values (+/- 1 SD) for best corrected VA at baseline were

OD: 46.5 (+/-17.6); OS: 49.7 (+/-17.3); OU: 62.2 (+/-16.0). Pass/fail criteria was arbitrarily set at 2 SDs below the combined baseline means, and Table 4 shows the percentages of subjects that failed these cut-off criteria when tested uncorrected, i.e., without best spectacle correction post-PRK. Comparatively, larger percentages of subjects failed this cut-off criteria post-PRK when tested uncorrected as compared to testing with best correction as shown in Table 5. As anticipated, when subjects were tested post-PRK with their best correction in a trial frame, the failure rates in general were similar to or even less than the pre-PRK corrected baseline levels.

Table 4. Percentages of PRK treated subjects that failed to pass target values for OD, OS, and OU when tested without correction (Uncorrected) at 4, 6, 12, and 24 months post-PRK. Target values were derived from 2 SDs below the mean baseline values calculated for all subjects combined, controls and treated, for testing with best spectacle correction in a trial frame (Corrected). Statistical significance was determined for each post-PRK evaluation time by comparing to baseline using Bonferroni Post Hoc Analysis. Significance denoted as (*) at .05, and (**) at .005.

	Pre-PRK	Post-PRK			
	Baseline	4 Months	6 Months	12 Months	24 Months
	Corrected N=99	Uncorrected N=36	Uncorrected N=48	Uncorrected N=62	Uncorrected N=56
OD	3.0%	22.2%**	17.4%**	24.2%**	17.8%**
OS	4.0%	35.3%**	25.0%**	26.2%**	17.8%**
OU	5.0%	23.5%**	23.9%**	21.0%**	12.5%

Table 5. Percentages, of PRK treated subjects that failed to pass target values for OD, OS, and OU when tested with best spectacle correction in a trial frame (Corrected) at 4, 6, 12, and 24 months post-PRK. Target values were set at 2 Standard Deviations below the means of the baseline values for all subjects combined, controls and treated, from testing with best spectacle correction in a trial frame (Corrected). Note that if a subject required no optical correction post-PRK, a plano lens was placed in the trial frame. No statistically significant differences were found at any post-PRK evaluation time compared to baseline values using Bonferroni Post Hoc Analysis.

	Pre-PRK	Post-PRK			
	Baseline	4 Months	6 Months	12 Months	24 Months
	Corrected N=99	Corrected N=72	Corrected N=78	Corrected N=72	Corrected N=56
OD	3.0%	8.2%	0.0%	2.8%	0.0%
OS	4.0%	4.2%	1.3%	2.8%	3.6%
OU	5.0%	4.3%	2.7%	1.4%	0.0%

The bottom line is that with the Rabin SLCT under low light mesopic laboratory conditions there were: (1) statistically significant decreases over time in uncorrected visual performance post-PRK as compared to pre-surgical baselines with best optical correction; (2) no significant differences over time in best-corrected visual performance post-PRK as compared to pre-surgical corrected baselines. These data confirmed that some of our subjects had mild to moderate residual refractive errors post-PRK that contributed to poor performance without correction. The prevalence in post-PRK eyes of low to moderate residual refractive errors, defined as equal to or greater than -0.50 diopters of myopia (spherical equivalent) on cycloplegic refraction, was 20%, 22%, 28%, and 26% at 4, 6, 12, and 24 months post-PRK respectively. Yet very few of these subjects wore corrective lenses (prevalence and magnitude of post-PRK residual refractive errors in our subjects will be reported in another volume). It is obvious that small residual refractive errors post-PRK can degrade mesopic contrast sensitivity for high frequency targets, even though photopic high contrast Snellen VA may still be 20/20. When tested with best optical correction, however, performance on the Rabin SLCT chart improved to as good as, or better than, pre-PRK baseline values. The fundamental question is whether most individuals, especially aviators, will wear relatively minor optical corrections in spectacles after refractive surgery. Failure to do so, however, may mean that certain parameters of visual performance are compromised. Finally, it should be noted that there is a great deal of variance in testing with the Rabin SLCT chart at mesopic light levels At times, the variance was more than 30 letters (3 lines of letters on the chart) on the monocular tests. With repeated measures on the control group, the variance improved but was still at least 20 letters or 2 lines on the chart. The inherent variability in the Rabin SLCT, when tested under mesopic light levels, may limit its efficacy for monitoring subtle quality of vision issues post-refractive surgery, or its use as a selection or return-to-cockpit standard.

Analysis of Mesoptometer Data

The data obtained with the Mesotest II b, which is defined as a test of mesopic contrast sensitivity for a low spatial frequency target, revealed some changes in performance post-PRK, especially for the testing without glare. Mesopic performance data, both pre- and post-PRK, are presented for slides #3 and #4 (without glare) and #7 and #8 (with glare). Slides #3 and #7, which have contrast values of 46%, are significant reference tests because they are recommended as pass/fail criteria by the Ophthalmological Society of Germany for attaining a class 2 (commercial) driving license (55). Likewise, slides #4 and #8 were included because passing this contrast level (33%), represents the most difficult task in the testing sequence. At this setting, the Landolt C target is at its lowest test contrast and may correlate more directly with operational conditions during night missions. Data from slides #1, #2, #5, and #6 were not included for analysis since they have higher contrasts and essentially everyone passed those slides at each testing time. Accordingly, only data from test slides #3, #4, #7, and #8 were presented in this section for analysis.

The data displayed in Table 6 shows the rounded off percentages of PRK-treated subjects passing mesopic trials #3 and #4 (without glare) and #7 and #8 (with glare) at pre-PRK baseline and 6, 12, and 24 months post-PRK for OD and OS. Note that subjects were always tested, both pre- and post-PRK, with their best spectacle correction in a trial frame. This monocular data revealed an overall trend, mostly at 6 months, for lower percentages of subjects to pass mesopic

test slides #3 and #4 after PRK than before. This trend of reduced mesopic visual performance in post-PRK treated subjects was statistically significant ($p = 0.05$) for both the OD and OS data on slide #3 at 6 months and on slide #4 for the OD at 6 months and OS at 12 months. The only other significant differences occurred with the glare testing slide # 7, which actually showed an improvement at 24 months compared to baseline. Possible reasons for an improvement over time with glare testing are as follows: learning effects over time on how to make subtle ocular fixation movements to locate the most sensitive part of the retina for maximizing target detection; training oneself not to gaze directly into the bright glare source; the bright light induced miosis of the pupil with optical pinhole effect. The main issue with regard to the glare test slides (#7 and #8) is that glare testing in general has inherent problems related to bright lights inducing pupillary constriction and creating an optical pinhole effect. A pinhole serves to minimize image degradation from residual refractive errors, secondary optical aberrations, and corneal defects. This induced miosis produces an innate improvement of, or may mask any decrement, in visual performance unless ocular media problems exist central to the visual axis. Accordingly, the mesopic glare test slides in this study were not found to be useful metrics for detecting subtle quality of vision problems post-PRK.

Table 6. The percentages of PRK treated subjects that passed with OD and OS each of mesopic tests #3 & #4 (without glare) and #7 & #8 (with glare) at baseline, 6, 12, and 24 months. All testing, both pre- and post-PRK, was done fully corrected with the best spectacle correction in a trial frame. Statistical significance was determined by using the McNemar Test for Matched Pairs comparing baseline data to post-PRK data at each respective evaluation time. Significance denoted as (*) at .05, and (**) at .005.

	Baseline		6 Months		12 Months		24 Months	
Mesoptometer	*N=79*		*N= 76*		*N= 72*		*N= 56*	
Monocular	*OD*	*OS*	*OD*	*OS*	*OD*	*OS*	*OD*	*OS*
Slide #3 (No Glare)	87%	85%	79%*	71%*	82%	82%	89%	84%
Slide #4 (No Glare)	70%	61%	58%*	60%	60%	51%*	66%	70%
Slide #7 (Glare)	75%	79%	82%	82%	82%	82%	89%*	91%*
Slide #8 (Glare)	61%	66%	63%	65%	62%	68%	64%	75%

The binocular data is shown in Table 7. Essentially, no statistically significant changes were found in the percentages of PRK treated subjects passing slides #3, #4, #7, and #8 over time after surgery, when compared to baseline values, except for slide #3 at 12 months post-PRK. Again, it should be noted that subjects were always tested, both pre- and post-PRK, with their best spectacle correction in a trial frame.

Table 7. The percentages of PRK treated subjects that passed binocularly each of mesopic tests #3 & #4 (without glare) and #7 & #8 (with glare) at baseline, 6, 12, and 24 months. All testing, both pre- and post-PRK, was done fully corrected with the best spectacle correction in a trial frame. Statistical significance was determined by using the McNemar Test for Matched Pairs comparing baseline data to post-PRK data at each respective evaluation time. Significance denoted as (*) at .05, and (**) at .005.

	Baseline	6 Months	12 Months	24 Months
Mesoptometer	*N=79*	*N= 76*	*N= 72*	*N= 56*
Binocular	*OU*	*OU*	*OU*	*OU*
Slide #3 (No Glare)	100%	97%	90%*	98%
Slide #4 (No Glare)	90%	83%	83%	93%
Slide #7 (Glare)	95%	100%	97%	100%
Slide #8 (Glare)	87%	95%	93%	93%

Table 8 provides some data comparing corrected versus uncorrected post-PRK mesopic visual performance in a small subset of subjects with minor residual refractive errors. It is clear that smaller percentages of post-PRK subjects passed slides #3 and #4 for OD, OS, and OU when uncorrected as compared to best corrected. Regrettably, the number of subjects tested without correction was small; however, it is readily apparent from the limited data that performance in post-PRK subjects uncorrected was much worse than when their performance was tested with best correction. Obviously, the negative effect and potential operational impact of low to moderate residual refractive errors not being corrected post-PRK can not be ignored. The prevalence in PRK treated eyes of low to moderate residual refractive errors, defined as equal to or more than -0.50 diopters of myopia (spherical equivalent) on cycloplegic refraction, was 21.6%, 28.5%, and 26.2% at 6, 12, and 24 months post-PRK respectively. Yet very few of these subjects wore corrective lenses. Accordingly, more work needs to be done over the long term to evaluate mesopic visual function in post-PRK patients with minor uncorrected residual refractive errors; especially those that may be able to "pass" a high contrast Snellen visual acuity test of only 20/20, i.e., barely pass aeromedical vision standards and be allowed to fly without optical correction. For comparison with the percentages shown in Table 8, the same subjects in this study were tested without correction on a traditional high contrast Snellen visual acuity test. The results revealed that only 5.5%, 3.9%, 4.9%, and 3.6% failed to pass that "clinical standard" at 4, 6, 12, and 24 months post-PRK respectively.

Table 8. The percentages for a small subgroup of treated subjects with minor residual refractive errors post-PRK that passed each of mesopic tests #3 and #4 (without glare) and #7 and #8 (with glare) at 12 and 24 months post-PRK. Testing was conducted both without (Uncorrected) and with (Corrected) best spectacle correction in a trial frame for OD, OS, and OU. Statistical analysis was not performed because of the limited number of subjects that were tested without optical correction post-PRK.

	12 Months Corrected		12 Months Uncorrected		24 Months Corrected		24 Months Uncorrected	
Mesoptometer	*N=8*		*N= 8*		*N= 24*		*N= 24*	
Monocular	***OD***	***OS***	***OD***	***OS***	***OD***	***OS***	***OD***	***OS***
Slide #3 (No Glare)	88%	75%	50%	12%	96%	100%	71%	67%
Slide #4 (No Glare)	62%	50%	25%	12%	75%	83%	62%	54%
Slide #7 (Glare)	75%	75%	50%	50%	88%	84%	67%	71%
Slide #8 (Glare)	50%	38%	25%	50%	62%	75%	54%	50%
Binocular	***OU***		***OU***		***OU***		***OU***	
Slide #3 (No Glare)	88%		62%		100%		96%	
Slide #4 (No Glare)	88%		50%		96%		83%	
Slide #7 (Glare)	88%		50%		96%		96%	
Slide #8 (Glare)	88%		50%		96%		79%	

The mesoptometer data presented in this section indicates the following: (1) in a subset of post-PRK individuals, monocular and binocular non-glare mesopic visual function was degraded because of minor uncorrected residual refractive errors; (2) more significantly, monocular mesopic visual performance in some PRK treated subjects was reduced, relative to pre-PRK baseline values, even when an optimal correction was used especially during the first 6 months post-PRK. Speculation of possible causative mechanisms for this post-PRK degradation, which may be potentially problematic for night operational flying conditions, include transient corneal haze, small or de-centered ablation zones, corneal desiccation (65), reduced tear film break-up times (66), and effects of minor uncorrected refractive errors. It could be anticipated that post-PRK evaluations closer to the date of surgery might have shown even greater decreases in mesopic vision (21, 43). Because the emphasis of this study was long-term, logistical issues and inherent constraints in scheduling subjects for continuing studies resulted in no mesoptometry data earlier than 6 months post-PRK being collected. Current efforts are now being initiated to address and evaluate the early short-term changes following refractive surgery.

Analysis of NVG Visual Acuity Data

Before presenting the results of the night vision goggle testing, the monocular data from the control group was used to assess any drop-off in NVG intensifier tube performance over time. As can be seen in Figure 8, monocular VA performance for controls on the Bailey-Lovie chart was relatively consistent over time and essentially equal for the right and left intensifier tubes. Only a very minor decrease can be observed in NVG performance over the 40 months of the study, which was not statistically significant. The change averaged about 0.5 letters per year in

each individual tube, and about 0.3 letters per year for binocular NVG visual acuity (not shown). Accordingly, there was no significant drop-off in either image intensifier tube performance with the NVG used over the duration of this study.

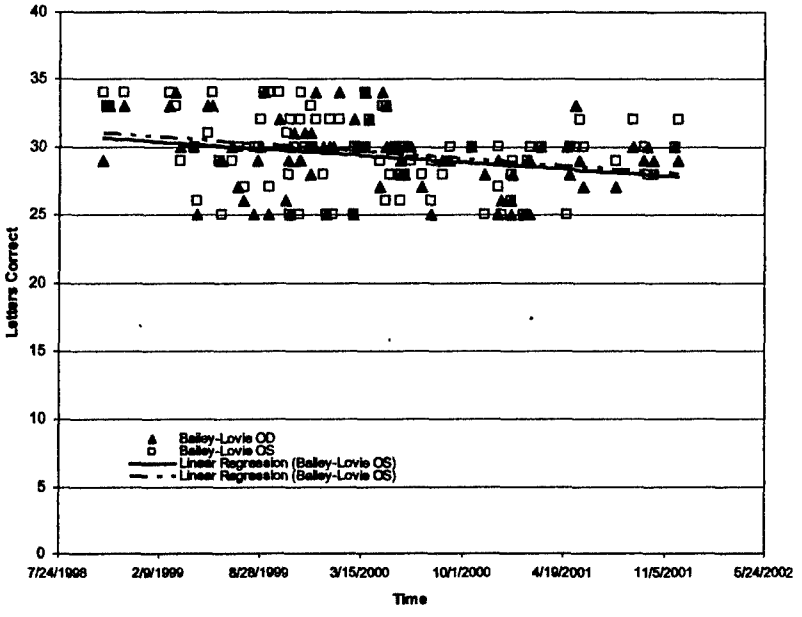


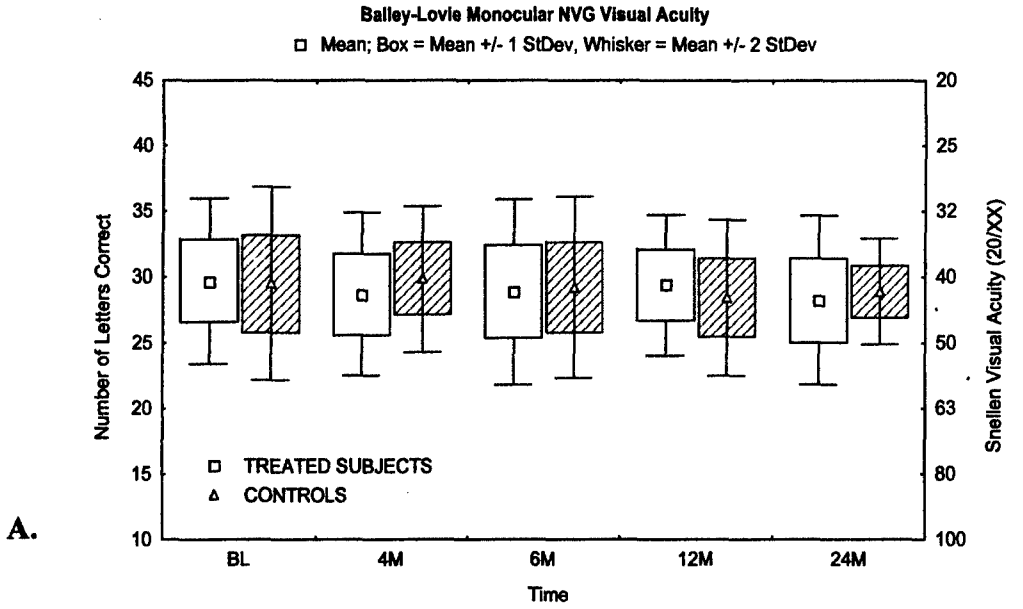
Figure 8. Monocular NVG performance by controls over 3 ½ years of data collection using the number of letters correctly identified on the Bailey-Lovie chart.

The results of the night vision goggle visual acuity (VA) testing were statistically analyzed using several methods: (1) ordinary means and standard deviations (SDs) were calculated for all experimental conditions at each evaluation time; (2) disparities in pass/fail rates between controls and treated subjects, and in treated subjects pre- and post-PRK, were calculated based on target VA values established from previous studies and USAF aeromedical visual acuity criteria for using NVGs (20/50 per Air Force Instruction 48-123, Aerospace Medicine: Medical Examinations and Standards); (3) to identify treated individuals potentially at risk for failing aeromedical standards post-PRK, performance was evaluated in a subset of poorer performing subjects by computing differences from baseline averaged over all evaluation times.

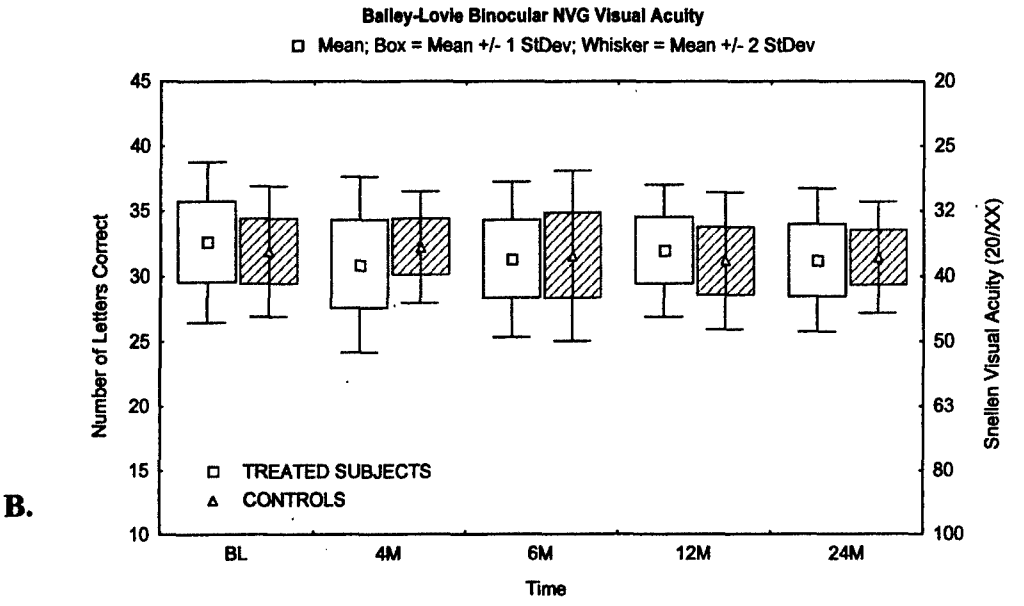
The data in Figures 9-11 is presented graphically by means of standard box-whisker plots that display group means and SDs for the Bailey-Lovie, High Contrast, and Low Contrast NVG charts respectively. A slight trend can be observed for NVG visual performance in treated subjects to be decreased at 4, 6, and 24 months post-PRK, but not at 12 months, especially for the monocular and binocular Bailey-Lovie data (Figure 9A and 9B). As previously noted, the only NVG data collected at 4 months post- PRK was with the Bailey-Lovie chart; no data was collected on the two NVG grating charts at 4 months. Statistical analyses of the data were subsequently performed using multiple paired-sample t-tests that compared baseline performance with each of the post-PRK evaluations. The p-value of .05 was adjusted for multiple t-tests which resulted in a p-value of .0125. Applying this adjusted p-value, the decreases in mean performance from baseline in the monocular Bailey-Lovie data were statistically significant at 4,

6, and 24 months. However, there was no statistical significance between baseline and 12 months. The Bailey-Lovie binocular testing showed exactly the same results for statistical significance at 4, 6, and 24 months, but not at 12 months. The data for the High and Low Contrast NVG Grid Charts (Figures 9 and 10) also reflected a small, although not statistically significant, decrease in treated group performance at six months after PRK that essentially mirrored the performance of the controls. These findings are particularly noteworthy because the corresponding data for controls in Figures 9-11 showed an opposite effect at each evaluation time, e.g., at 4 months controls performed better than at baseline. The slight improvement demonstrated by the control group may represent a learning effect, which was not evident in the PRK treated group. If such a learning effect did occur in treated subjects as well, then NVG performance post-PRK may actually be poorer than it appears in this data.

A curious finding on all NVG test charts, and identifiable in Figures 9-11, was that a relative increase in performance of treated subjects was found at 12 months, but a decrease in performance occurred at 24 months. This trend was observed in other results from the comprehensive PRK Study as well (26, 67, 68). However, an opposite trend was found in controls. This phenomenon is difficult to explain but it could be speculated that some changes may not be manifested until 2 years after PRK, e.g., late-onset corneal haze, changes in tearfilm dynamics, desiccation keratitis, sub-clinical healing, or atrophic change, etc. Perhaps it was the result of older technology and different surgical techniques (9). More recently, however, a similar trend was also noted in Air Force pilots treated early in the USAF Aviation PRK Program using newer generation technologies that was not present in patients treated later (69). Future studies will address this issue.



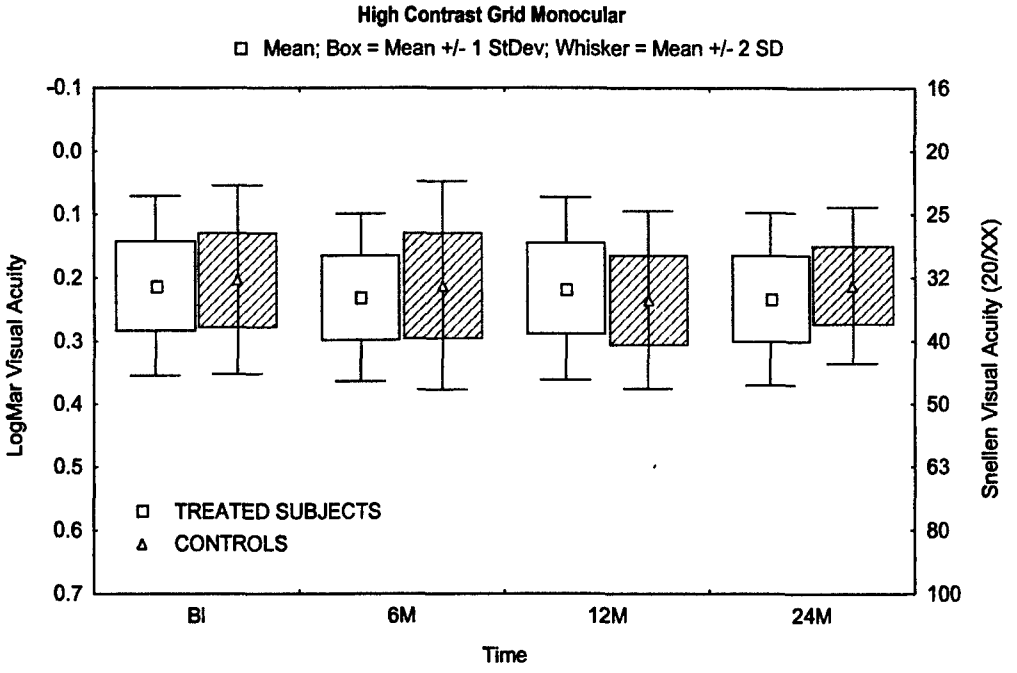
A.



B.

Figure 9. Means and standard deviations for controls and treated subjects from testing with the Bailey-Lovie chart for (A) monocular and (B) binocular NVG visual acuity.

A.



B.

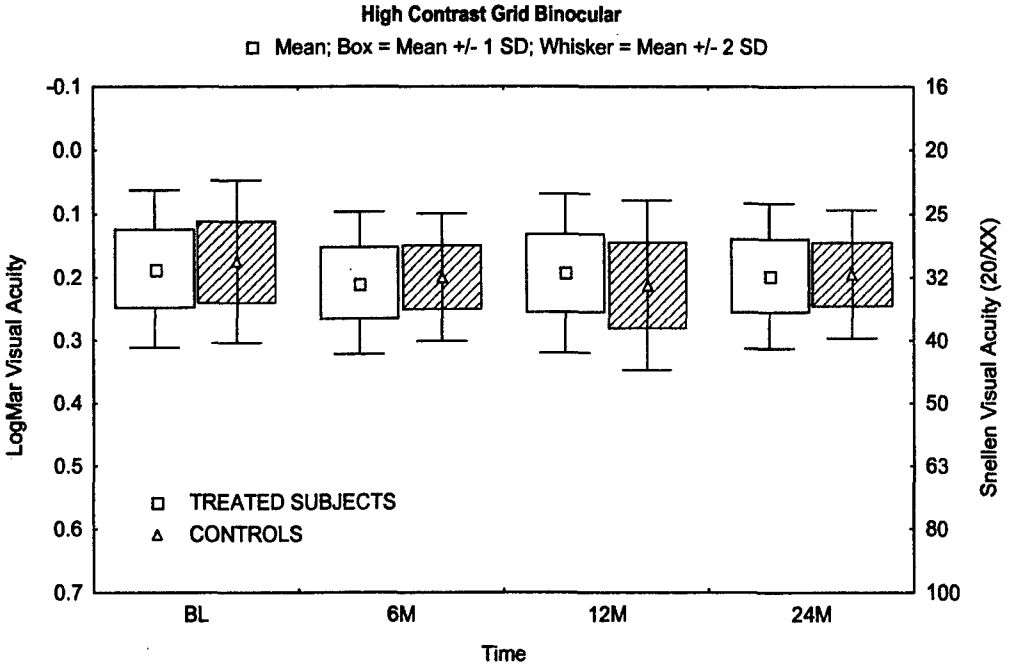


Figure 10. Means and standard deviations for controls and treated subjects on the NVG High Contrast Grid Chart for (A) monocular and (B) binocular NVG visual acuity.

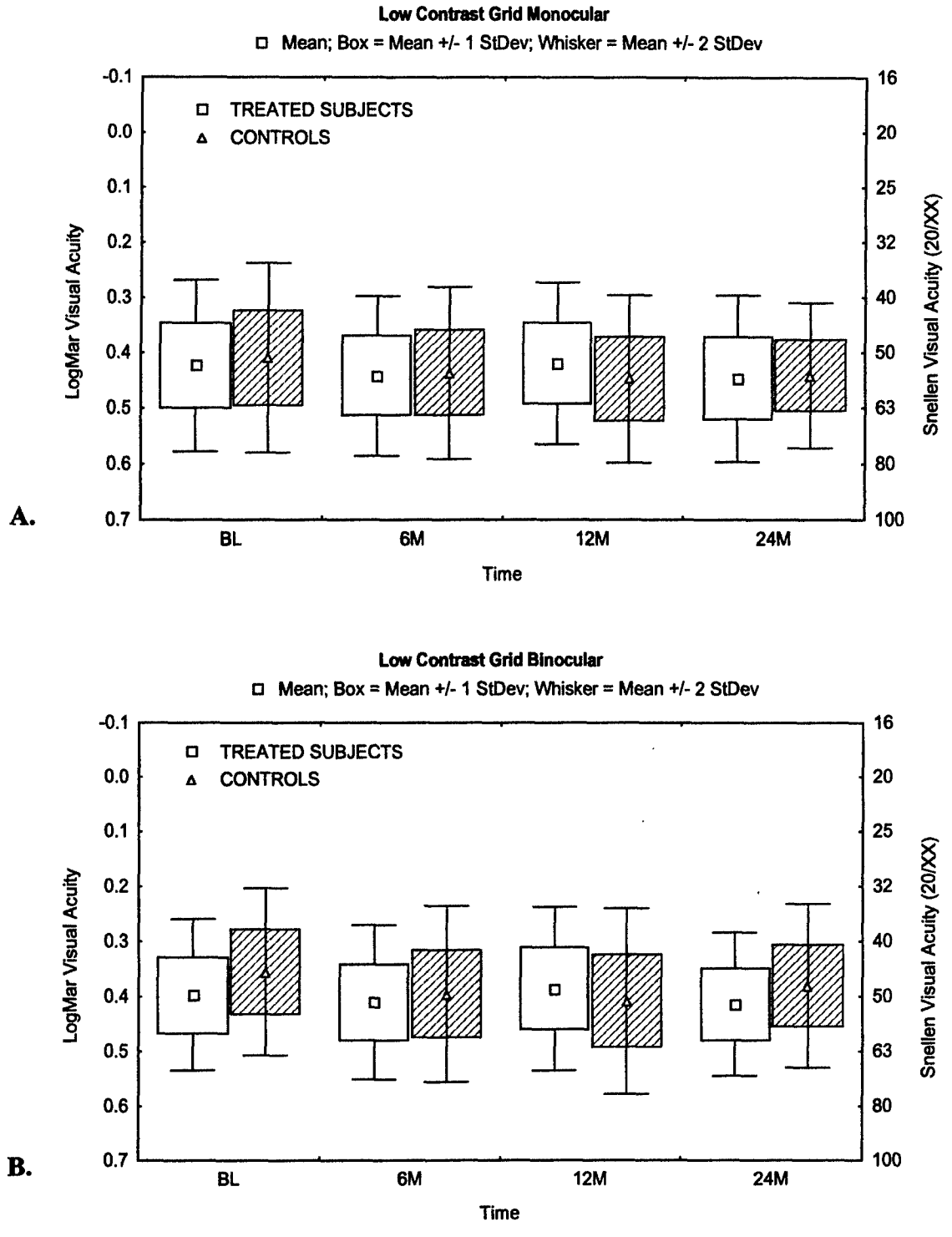


Figure 11. Means and standard deviations for controls and treated subjects on the Low Contrast Grid chart for (A) monocular and (B) binocular NVG visual acuity.

The next component of the data analysis was based on previously published NVG research studies (36-44), including three conducted by the Aerospace Ophthalmology Branch of the USAF School of Aerospace Medicine (or Armstrong Laboratory), and data from this study (67) for the initial pre-surgical baselines. This data provided a solid basis for developing pass/fail

target criteria, which was applicable to subjects tested under the exact experimental conditions in our night vision laboratory and using similar F4949G model (ANVIS-9) NVGs. Although any cut-off criterion represents an arbitrary standard, the target pass/fail values for NVG visual acuity performance used here essentially equated to 2 SDs below the means from several studies. Thus, the target visual acuity values compared favorably with values from similar NVG research studies, both in-house and from other laboratories, and approximated current USAF aeromedical criteria. Note that there are currently no formal aeromedical standards for NVGs, but the recommended criteria is at least 20/50 for minimal operational performance with NVGs, as found in Air Force Instruction 48-123, Aerospace Medicine: Medical Examinations and Standards.

Once the target minimum VA standards (20/xx) were set for each NVG test chart, illumination level, and monocular/binocular condition, they were then applied to the experimental data collected at each evaluation session to identify the number (and percentage) of subjects that failed to achieve these levels of VA. The specific target visual acuity used for each condition is listed in the description below each Table. Accordingly, the data is displayed in Table 9 below for monocular (OD and OS data combined) VA performance, and in Table10 for binocular VA performance. The three experimental conditions for NVGs were: (1) the Bailey-Lovie chart at quarter moon; (2) the High Contrast NVG Grid Chart at quarter moon; (3) the Low Contrast NVG Grid Chart at starlight. The percentages of eyes or subjects that failed to achieve the target minimum VA, both pre- and post-PRK, are shown. These data provide a comparison to pre-PRK baseline corrected values of the percentages of post-PRK treated subjects, tested with best correction that failed to achieve the respective target VA values at each evaluation time.

As can be seen in Table 9, the monocular NVG data shows that a higher percentage of treated subjects failed to pass the appropriate target VA post-PRK as compared to the pre-PRK baseline values, especially with the Bailey-Lovie chart. Statistical analysis for both tables was conducted by comparing the post-PRK values at 4, 6, 12, and 24 months respectively to the initial baseline value using a test for differences between two proportions (* denotes significance at .05; ** denotes significance at .005). The monocular Bailey-Lovie testing shows that the increased post-PRK failure rates were statistically significant at 4, 6, and 24 months but not at 12 months.. The High Contrast NVG Grid Chart testing had no statistically significant results, while the Low Contrast NVG Grid Chart testing identified some statistically significant differences from baseline values at 6 and 24 months post-PRK but not at 12 months.

Table 9. Percentages of eyes in treated subjects with monocular NVG visual acuity worse than 20/50 on the Bailey-Lovie chart, 20/45 on the High Contrast Grid Chart, and 20/70 on the Low Contrast Grid Chart (* denotes statistical significance at .05; ** denotes statistical significance at .005).

Monocular	Baseline	4 Months	6 Months	12 Months	24 Months
Number of Eyes	*153*	*145*	*154*	*143*	*112*
Bailey-Lovie	**2.0%**	**6.2%***	**9.1%****	**4.9%**	**8.9%****
HC NVG Grid	**1.3%**	**xx**	**3.2%**	**1.4%**	**2.7%**
LC NVG Grid	**3.2%**	**xx**	**8.4%***	**2.8%**	**8.0%***

Likewise, Table 10 shows the same type of trend for the NVG binocular VA testing. The binocular Bailey-Lovie testing shows that the increased failure rates post-PRK were statistically significance at 4 and 6 months, but not at 12 and 24 months. The High Contrast NVG Grid Chart testing had no statistically significant results, while the Low Contrast NVG Grid Chart testing identified statistically significant differences from baseline values at 6, 12, and 24 months post-PRK.

Table 10. Percentages of eyes in treated subjects with binocular NVG visual acuity worse than 20/45 on the Bailey-Lovie chart, 20/40 on the High Contrast Grid Chart, and 20/60 on the Low Contrast Grid Chart (* denotes statistical significance at .05; ** denotes statistical significance at .005).

Binocular	Baseline	4 Months	6 Months	12 Months	24 Months
Number of Ss	*77*	*66*	*75*	*72*	*56*
Bailey-Lovie	**1.3%**	**16.7%****	**10.0%***	**5.5%**	**5.0%**
HC NVG Grid	**2.6%**	**xx**	**6.7%**	**2.8%**	**1.8%**
LC NVG Grid	**4.0%**	**xx**	**10.7%***	**11.1%***	**14.3%***

Although the changes in group means shown in Figures 9-11 were statistically significant, the mean data suggests only minor degradations in performance, which in general would probably not be operationally significant. However, group means can mask large variation in individual subjects. There could be changes in a subset of individuals with potential operational significance; accordingly, the existence of a poorer performing subset is of primary interest. The data presented in Figure 12 shows the average number of letters gained or lost over time by individual subjects in the PRK treated group for the NVG testing with the Bailey-Lovie chart. These data display mean fluctuations from baseline values, averaged across the 4, 6, 12, and 24 months post-PRK evaluations, for OD and OS. Applying a common clinical criteria for

significant change, e.g., a loss of greater than one line of letters, which corresponds to 5 letters on the Bailey-Lovie chart, it can be observed that more subjects lost a line of acuity than gained a line on average over time post-PRK. Of the 154 treated eyes, 17 (11.0%) showed a loss of more than 5 letters (averaged over 2 years) as compared to only 4 (2.6%) that showed a gain of more than 5 letters. If 11% of treated eyes have consistently degraded NVG performance after PRK, this could translate into an unacceptable impact on operational readiness and mission effectiveness. By comparison, none of the control subjects had an average loss of more than one line of letters.

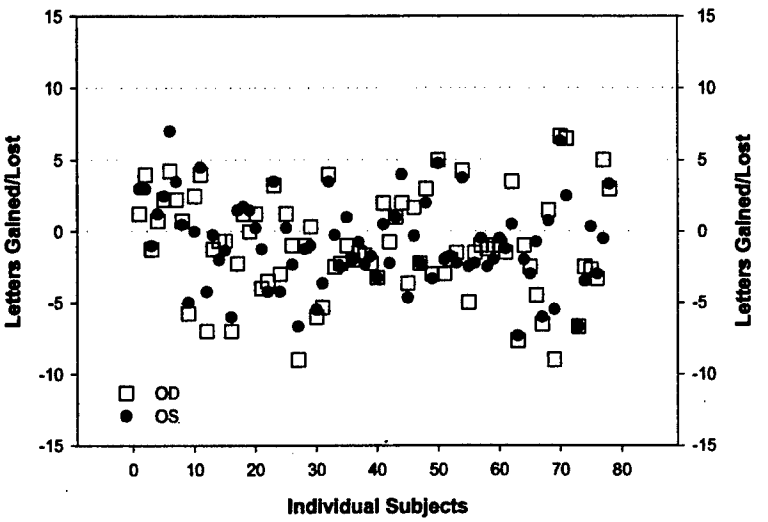


Figure 12. Number of letters lost or gained from pre-PRK baselines, averaged over all post-PRK evaluation times, for monocular Bailey-Lovie NVG testing.

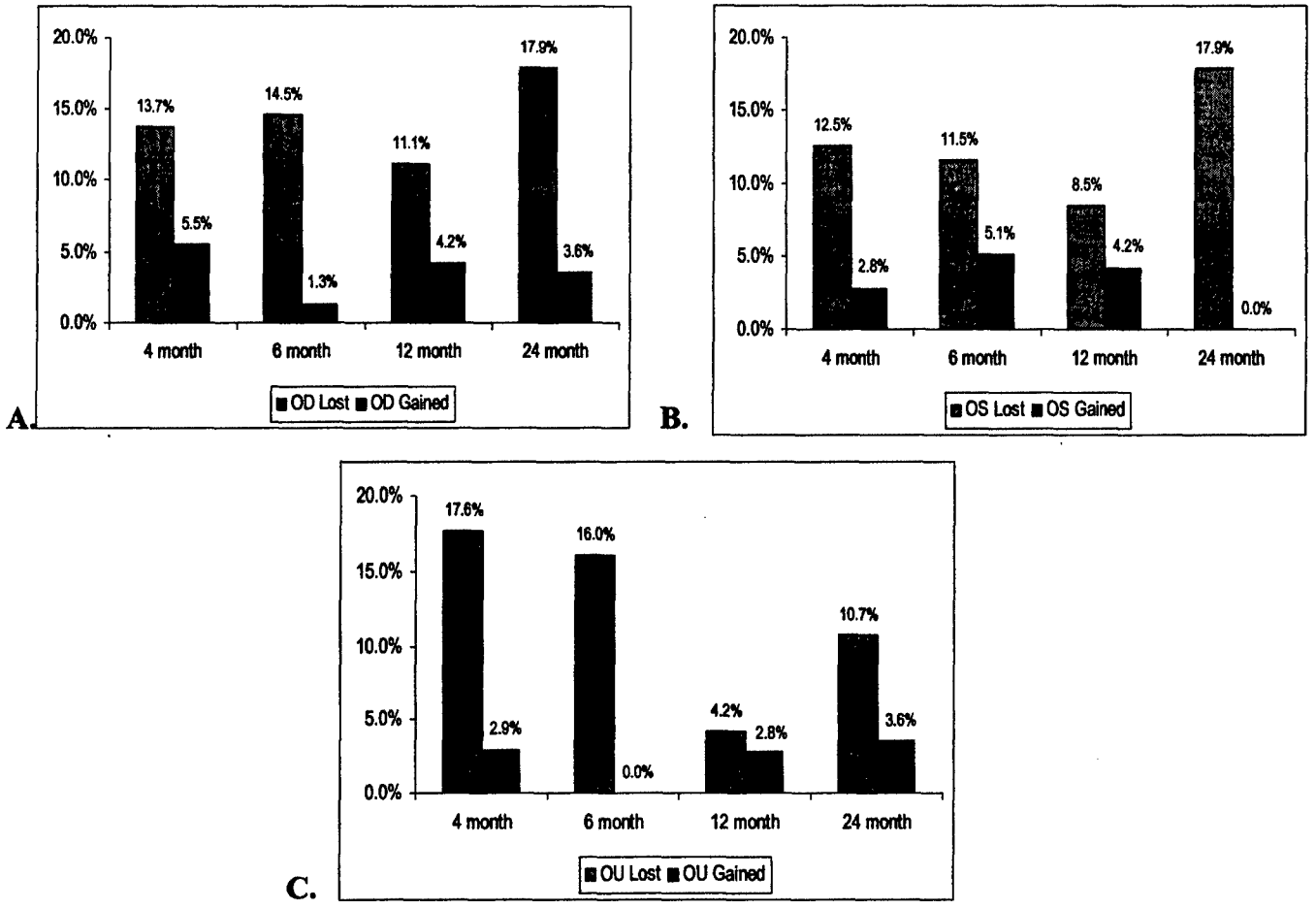


Figure 13. Percentages of post-PRK subjects that lost, or gained, more than 1 line of letters (6 letters or more) from their baseline NVG visual acuity on the Bailey-Lovie Chart at each evaluation time (Fig. A, B, and C correspond to OD, OS, and OU respectively).

Figure 13 displays the data, in terms of percentages, for treated subjects that lost, or gained, more than one line of letters from their pre-PRK baseline at each post-PRK evaluation time. It can be readily observed that there are more subjects that lost over one line than gained. The subset of subjects that lost more than one line of letters, at one or more post-PRK evaluation times, included 26 right eyes, 23 left eyes, and 23 subjects that surprisingly failed the binocular (OU) testing. There was no pattern or consistent causative factor that could be identified for these poorer performing subjects, including correlation with corneal topographical changes, e.g., central islands or decentered ablatins, and they were scattered evenly throughout the four treated subgroups (discussed on page 6) of this study. Future publications are planned to address these causative factors. The end result is that this poorer performing subset may represent a potentially large attrition rate for operational readiness and/or flight safety.

A subtle, but potentially operationally significant, post-PRK drop off in night mesopic and/or NVG performance can only be detected by using a battery of highly sensitive tests that measure

several components of night mesopic and NVG vision. High contrast Snellen eyecharts are too coarse to detect or identify these changes. The exact mechanisms for why NVG capability is decreased post-PRK remains unclear, but it is most likely related to degradation in overall optical image quality from interplay of multiple potential causes, including PRK induced spherical aberrations, double-edge pupil effect, tear film anomalies, light scattering, and corneal haze. The 4 month Bailey-Lovie data was important because physiological healing effects, e.g., corneal haze, microcystic edema, desiccation, etc., were more likely to be present. Also, the negative effect of large pupils may be a factor in some individual cases. Brightness output levels in current NVG tubes are usually high enough to result in sufficient miosis in most individuals to avoid peripheral aberrations and/or a double-pupil edge effect from the surgical ablation zone. However, certain mydriatic factors may run counter to light induced miosis and override parasympathetic input in young aviators, e.g., medications, adrenergic excitation levels, etc. Even with newer surgical techniques or procedures, optical quality and light scatter from large pupils will continue to remain significant night vision issues after any refractive surgery procedure (67). Accordingly, excessively large pupils preoperatively may be a contraindication for aviators that use NVGs operationally. The bottom line is that regardless of the etiology, any decrease in NVG performance may have significant operational relevance, particularly with regard to trained aviators who elect to have PRK and fly at night or are required to participate in NVG night missions.

Also notable is the fact that the degradation in NVG visual acuity from uncorrected residual refractive errors post-PRK was not evaluated in this study, especially from the perspective of evaluating return to cockpit decisions after PRK. All NVG testing, including all post-PRK evaluations, was conducted with subjects wearing their best spectacle correction in a trial frame (usually Rxs of low power). Plano trial lenses were used when subjects required no optical correction at all, which was very infrequent. Accordingly, there is no NVG data collected on post-PRK subjects without best optical correction in place. Although NVGs can be focused to correct myopia and hyperopia, there is no means for correcting astigmatism. Figure 14 shows the percentages of eyes that had 0.75 Diopters or more of astigmatism (cylinder power) on cycloplegic refraction at each post-PRK evaluation time. Visual acuity with NVGs may be degraded at or above this amount of uncorrected cylinder (1, 2, 39, and 42). It is readily apparent that fairly large percentages of eyes would not be able to optimally perform with NVGs if astigmatism was not corrected by PRK and optical correction was not subsequently worn. Therefore, uncorrected post-PRK data would be extremely valuable for evaluating NVG visual performance under more realistic operational conditions. This is because it is very unlikely that aviators will wear minor to moderate astigmatic corrections post-PRK when performing flying duties, especially if they can meet the less sensitive 20/20 Snellen based aeromedical standard.

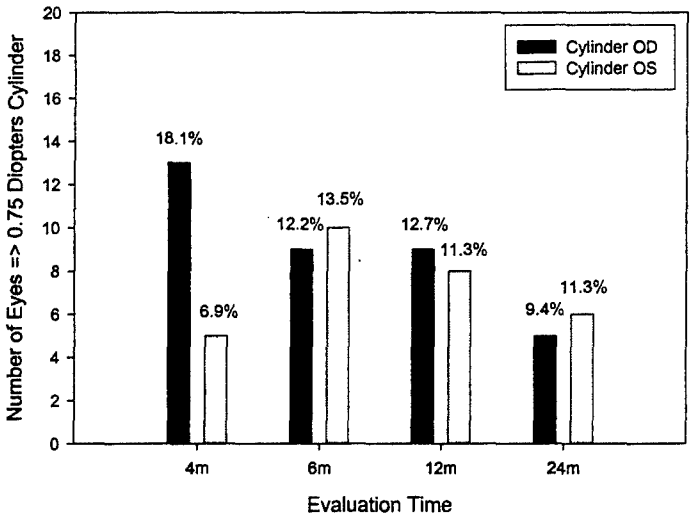


Figure 14. Number of eyes, and percentages of total, with 0.75 Diopters or more of astigmatism (cylinder) on cycloplegic refraction at each post-PRK evaluation time.

The implication of all these findings are as follows: (1) NVG performance at baseline and especially post-PRK needs to be assessed in the field as a part of any return-to-fly decision in those trained aviators who use NVGs, or may need to use them in the future; (2) in order to preserve mission readiness, effectiveness, and flight safety after PRK, there is clearly a need to establish general NVG performance standards, extrapolated from a normative database, that will serve to identify poor performers and, especially, less than optimal outcomes after refractive surgery; (3) predictive models should be developed that will assess and identify the potential for less than optimal outcomes based upon pre-surgical parameters; (4) post-PRK spectacle correction may be required to optimize visual performance in a subset of aviators, even if they can "pass" traditional high contrast visual acuity standards; (5) further study of the impact of refractive surgery on NVG performance is warranted, especially for uncorrected visual acuity with NVGs, as future generations of night vision devices and newer emerging types of refractive surgery continue to evolve.

SUMMARY

In a 31 Jul 1995 Memorandum entitled "Visual Enhancements for USAF Aviators," the Chief of Staff of the USAF directed that Armstrong Laboratory develop tests that detect the complications of PRK, and that the Air Force Medical Operations Agency (AFMOA) was responsible for developing new aeromedical standards applicable for PRK if required. Accordingly, the Aerospace Ophthalmology Branch designed a comprehensive scientific study to evaluate the then novel surgical procedure of PRK. The results were to be used to determine the appropriateness of PRK for USAF aviators and, if it was proven safe and effective, to form the basis for developing new aeromedical standards appropriate for this procedure. It should be stressed that aeromedical criteria for operational flying is much different than standard clinical criteria in the civilian community. Problems that are termed minor or inconsequential by the

civilian community may become potentially life threatening in military environments. USAF pilot's and aviators are an extremely valuable resource and their health and safety must be vigilantly protected. Accordingly, the job of the Aerospace Ophthalmology Branch at the USAF School of Aerospace Medicine is to be a sentinel for aviators and ensure that nothing is done that might degrade vision or ultimately affect flying performance. This study, which was part of the larger USAF comprehensive PRK study (26, 68), was specifically designed to expose any negative effects on night mesopic and NVG visual performance.

This study was a 24 month prospective evaluation of mesopic night visual performance that incorporated several measures of low light vision including night vision goggle visual acuity. The intent was to detect and identify subtle changes that may have been induced by PRK surgery, or its sequela, in the operationally important areas of mesopic vision and NVG performance. Specifically, three mesopic parameters were evaluated that simulated a broad range of operational night visual performance conditions: (1) high spatial frequency mesopic contrast sensitivity was measured using the Rabin Small Letter Contrast Test (SLCT) chart at low light levels; (2) low spatial frequency mesopic contrast sensitivity was measured using a mesoptometer (Mesotest II b) both without and with glare; (3) NVG visual acuity was tested using an ANVIS-9 model F4949G to view 3 different visual acuity charts at two ambient light levels.

Results from testing with the SLCT chart revealed no statistical differences for pre- and post-PRK testing providing the PRK-treated subjects were tested with their best spectacle correction in a trial frame, i.e., when post-PRK residual refractive errors were corrected. In fact, a small trend toward improvement was present in small letter contrast sensitivity performance post-PRK, but this equated to a difference of only a few letters and was not statistically significant. When treated subjects were tested without correction, however, post-PRK performance on the SLCT was decreased at each time period despite the inherent variance in the SLCT results.

Recent estimates, even with the latest treatment algorithms, show that from 5% to 30% of post-PRK patients will require spectacles at some point in time during their flying career, depending upon how well the surgical program and pre- and post-surgical care is controlled. This finding may have great operational significance because it is unlikely that aviators will wear minor, or even moderate, spectacle corrections after PRK. Therefore, small uncorrected residual refractive errors after PRK surgery may translate into reduced mesopic visual performance during night missions. Consequently, some assessment of mesopic visual function should be performed as part of the aviator selection process, return-to-fly decision after refractive surgery, and periodically thereafter.

Results from the Mesotest II b testing without glare also showed some effects in post-PRK mesopic visual performance when subjects were tested without being optimally corrected in a trial frame. Data comparing mesopic visual performance in PRK treated subjects, with and without best correction in a trial frame, revealed a critical drop-off in uncorrected visual performance at 12 and 24 months post-PRK. Although the uncorrected data was based on a limited sample, it confirms that minor uncorrected refractive errors may also have a detrimental effect on this aspect of mesopic vision. A more disturbing finding, however, was that larger percentages of the treated subjects failed mesoptometry testing at 6 and 12 months post-PRK

when compared to control or their own baseline data. This occurred even when testing was conducted with subjects viewing through their optimal refractive correction in a trial frame. This decrement in performance was statistically significant for some of the test slides at 6 and 12 months post-PRK, for the monocular data; but, it was not statistically significant at 24 months, or for any of the binocular data with one exception. Unfortunately, 4 months post-PRK mesoptometer data, which might have shown an even greater effect, was not collected for reasons mentioned earlier.

Testing with the Mesotest II b using the glare conditions was also conducted. Results in general showed some slight improvements post-PRK, but degraded performance was generally found when post-PRK uncorrected performance was compared with post-PRK best corrected (Table 8). However, the fixed glare source test system used here possesses many of the same problems inherent to any glare tester of mesopic thresholds including: fixation in a glare field is tricky but extremely critical for best performance; a learning effect, or chance fixation at an optimal location may artificially improve performance and vice versa; lenses, especially trial lenses, positioned in front of the eye may create reflections that can actually degrade performance rather than improve; a bright glare source will induce pupillary miosis, which in turn causes a natural pinhole effect that innately improves vision and neutralizes the effects of refractive errors and optical aberrations. Because of these factors, data from the mesopic vision with glare tests on the Mesotest II b was not considered to be a useful measure of post-PRK performance.

The NVG test results revealed that, compared to pre-surgical baseline levels, higher percentages of subjects failed to pass credible benchmark visual acuity standards at many post-PRK evaluation times. The percentages of failures were usually higher at the 4 and 6 months post-PRK evaluations than at 12 and 24 months. This trend was present for VA measurements with the Bailey-Lovie and High Contrast NVG Grid Charts under simulated quarter moon ambient conditions, as well as the Low Contrast NVG Grid Chart testing under starlight illumination. The degradation in NVG visual performance was especially prominent when binocular vision was presented in Table 10, e.g., the failure rate on the Bailey-Lovie chart for binocular VA at baseline (pre-PRK) was 1.3%, while it was 16.7%, 10.0%, 5.5%, and 5.0% at 4, 6, 12, and 24 months respectively In addition, a subset of subjects and eyes was identified that lost more than one line of letters, which was much larger than the subset that gained more than one line off letters (Figure 13). Poorer performing subjects that lose more than one line off letters after PRK may fail to meet NVG aeromedical criteria for flying and create operational readiness and/or flight safety issues.

These findings are even more remarkable because all NVG testing was performed with subjects wearing their optimal spectacle correction in a trial frame, both pre- and post-PRK. If the NVG testing had been conducted without correction at the post-PRK evaluations, it is likely that greater failure rates would have been reported because of the inability of the NVG focusing system to correct for astigmatism and other optical side-effects from PRK.

The negative effect and potential operational impact of low to moderate residual refractive errors not being optimally corrected in aviators after any refractive surgery must be addressed. The prevalence in this study for PRK treated eyes to have low to moderate residual refractive errors, defined as equal to or more than -0.50 diopters of myopia (spherical equivalent) on cycloplegic

refraction, was 20%, 22%, 28%, and 26% at 4, 6, 12, and 24 months post-PRK respectively. Yet very few of these subjects wore corrective lenses. Larger amounts of pre-operative myopia outside the criteria of this study would be expected to have less likelihood of achieving emmetropia post-PRK. On the other hand, new treatment technologies would be expected to counter some of that trend. Regardless, more work needs to be done over the long term to evaluate mesopic visual function in post-PRK patients with minor uncorrected residual refractive errors; especially those that may be able to "pass" a high contrast Snellen visual acuity test of only 20/20, i.e., barely pass aeromedical vision standards and be allowed to fly without optical correction. For comparison with the data shown in Tables 2, 4, and 8, the same subjects in this study were tested without correction on a traditional high contrast Snellen visual acuity test. The results revealed that only 5.5%, 3.9%, 4.9%, and 3.6% failed to pass that "clinical standard" at 4, 6, 12, and 24 months post-PRK respectively. If post-PRK testing is limited to only high contrast Snellen visual acuity, mesopic night and NVG problems may be missed in a subset of individuals.

These results raise several potential operational concerns about NVG and mesopic night vision performance in post-PRK aviators that will also apply to any refractive surgery done in the future. First, night or NVG mission performance may be reduced if aviators are not identified and required to wear minor to moderate spectacle corrections post- refractive surgery. Second, mesopic and/or NVG vision in some post-refractive surgery aviators may be compromised from pre-surgical levels, even if the optimal spectacle correction is provided. Third, aeromedical standards for mesopic and NVG visual performance should be established for all aviators and monitored on a regular basis, particularly after refractive surgery, to ensure mission effectiveness and flight safety both short- and long-term.

In conclusion, a range of mesopic night vision and NVG parameters were evaluated to detect potential negative effects post-PRK with the following results: (1) when PRK treated subjects were tested over a 24 month follow-up period, post-PRK uncorrected mesopic visual performance was found to be reduced from pre-PRK baseline corrected performance; (2) compared to pre-PRK baseline corrected performance, after PRK more subjects failed the Mesotest II b and/or NVG target visual acuities even when testing was conducted with best spectacle correction.

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